Report on the Investigation into the Cause or Source of an Actual or Potential Accident under the Provisions of Paragraph 1, Article 23 of the Consumer Safety Act

Airway obstruction accidents due to toys in infants

November 20, 2017

Consumer Safety Investigation Commission

The investigation included in this report is intended for the Consumer Safety Investigation Commission to clarify the cause of accidents and cause of harm with a view to ensuring consumer safety under the Provisions of Paragraph 1, Article 23 of the Consumer Safety Act. Investigations or evaluations by the Consumer Safety Investigation Commission are intended to prevent instances of harm to consumers involving bodily harm from occurring or increasing. It is not the purpose of the investigation to apportion blame or liability.

This report was finalized by the Consumer Safety Investigation Commission on November 20, 2017 through investigations by the assigned expert members and investigations and discussions by the Accident Investigation Subcommittee for Products, etc.

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Note:
This report is a translation of the Japanese original investigation report. The text in Japanese shall prevail in the interpretation of the report.

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Summary of the Report

The Investigation Commission received a filing for the investigation into the cause or source of an accident in which a 9-month-old boy choked on a toy (with a diameter of approximately 10 mm) of his sibling (a young child) and died.
This filing prompted the Investigation Commission to select airway obstruction accidents due to toys in infants as subjects of an investigation into the cause or source with an emphasis on the following elements in accordance with “Guidelines for Selection of Subjects of Investigations or Evaluations” (Consumer Safety Investigation Commission Decision of October 3, 2012).

- Toys have a highly “public nature,” because they are widely used in the daily life of infants.
- “Extent of harm” is significant, because fatal accidents due to airway obstruction have occurred.
- Mainly infants, individuals who require special consideration from the viewpoint of ensuring consumer safety, suffer or may suffer harm (“Focus on those who require consideration”).

<Conclusion>

The questionnaire survey among parents/guardians to determine what age groups (in month) of children experience aspiration and what types of toys were aspirated demonstrated that such accidents frequently occurred in infants younger than three years, especially those aged between six months and one year and six months. In addition, “marbles” was the most common type of toys, followed by “bead-based toys” and “small balls.” For the size, “6 to 10 mm” was the most common, followed by “11 to 20 mm” and “0 to 5 mm.” For the shape, “objects of the same size when viewed from any plane (such as spheres and cubes)” was the most common, followed by “flat objects.”
It is probable that the behavioral characteristic of “putting anything in the mouth,” observed especially in infants, also contributes to aspiration of toys. In addition, physical characteristics of infants, such as the size of the pharynx smaller than the maximal mouth opening, the mouth close to the throat, much saliva, and inadequate ability to expel (swallow/vomit) something that lodges in the throat on their own, also may prompt an aspirated toy to lodge in the throat (pharynx/larynx) to cause airway obstruction.

To elucidate the mechanism of such airway obstruction due to toys, as well as to gain insights into the size or shape of toys that caused airway obstruction, the airway obstruction simulation and airflow simulation analyses were performed using the CT images and videofluoroscopic images of swallowing from a nine-month-old child.

These analyses showed that all the shapes, that is, the sphere, hemisphere, ellipse, cuboid, cube, and block toy, caused complete airway obstruction and posed a high risk of choking. The rugby ball shape and peanut shape, as well as the sphere, caused pharyngeal obstruction-type choking when they were large in size and laryngeal obstruction-type choking when they were small in size. On the other hand, the cuboid, cube, and block toy did not cause complete obstruction of the pharyngeal cavity because some space was left in the pharyngeal cavity; however, they blocked the laryngeal aperture by applying downward pressure to the epiglottis from above.

In addition, these simulations also suggested that toys that were unlikely to cause obstruction of airway (pharynx/larynx) based on their size or shape may stay in the pharynx or larynx together with liquid to cause airway obstruction and therefore asphyxiation when they entered the pharynx or larynx, mixed with viscous liquid.

The questionnaire survey among parents/guardians suggested that some toy-related enterprises may design and manufacture toys or specify and indicate the intended age without regard to standards for the safety of toys, even though toys familiar to infants may obstruct the airway to cause asphyxiation. It is also possible that parents/guardians do not fully understand that intended ages are determined with regard to the development of children and safety aspects.

It was also found that the “back blow maneuver” and “Heimlich (abdominal thrust) maneuver,” actions to be taken in case of accidents, were not pervasive in home settings, although they are recommended in maternal and child health handbooks or local life-saving training sessions are held.

In addition, it was found that a certain number of accidents of aspiration of toys occurred, while information on accidents was not shared among toy-related enterprises and administrative bodies.

<Opinions>

1 Opinions for the Minister of Economy, Trade and Industry

(1) Dissemination of the Risk of Accidents

The Ministry of Economy, Trade and Industry should encourage toy-related enterprises to understand the behavioral characteristics of infants, structure of the mouth or characteristics of swallowing, and characteristics of toys that potentially cause aspiration or choking in order to manufacture or sell safe toys. To that end, the Ministry should continuously and widely disseminate the behavioral or physical characteristics of infants to toy-related enterprises by reference to this report and the Investigation Commission-produced movie titled "Protection of children from choking accidents" and papercraft "Model of the infant's mouth and throat."

(2) Design, Manufacture, and Sales of Safe Toys

(a) The Ministry of Economy, Trade and Industry should encourage toy-related enterprises to ensure that intended ages should be determined and indicated based on standards or international standards for safety of toys, including ST Standard. In addition, the Ministry should verify the effectiveness of the encouragement and should consider further measures if adequate effectiveness is not achieved.

(b) The Ministry of Economy, Trade and Industry should make efforts to ensure that safe toys are designed, manufactured, and sold by asking toy-related enterprises to implement the following efforts:

i) For toys intended for children under three years that are in shapes classified as the sphere, such as the sphere, hemisphere, or ellipse, further safety improvement should be considered by making approaches such as using combinations of various test methods, such as a combination of the "small parts" test and the "small balls" test, designing toys with the assumption that they may be broken into small pieces even if such a design is considered unnecessary considering intended ages, and making as large holes as possible in multiple directions for avoiding airway obstruction and subsequent asphyxiation if a toy enters the throat (pharynx and larynx).

ii) The meanings of intended ages and safety labels such as the ST Mark should be communicated to consumers clearly and accurately.

2 Opinions for the Director General of the Consumer Affairs Agency

(1) Dissemination of the Risk of Accidents

The Director General of the Consumer Affairs Agency, as a control tower for prevention of accidents in children, should work with the Cabinet Office, Fire and

Disaster Management Agency, Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labour and Welfare, and other appropriate organizations to continuously and widely disseminate the risk of accidents to consumers so that consumers can gain a detailed understanding of the behavioral and physical characteristics of infants, characteristics of toys that potentially cause aspiration or choking, or the risk of accidents by reference to the Investigation Commission-produced movie titled "Protection of children from choking accidents" and papercraft "Model of the infant's mouth and throat" and other materials.

(2) Efforts to Disseminate Accident Preventive Measures

The Consumer Affairs Agency should make efforts leading to specific actions of consumers to prevent accidents, including dissemination of the accident preventive measures to consumers:

1) Since even toys of sizes and shapes that are unlikely to cause choking may cause choking when mixed with viscous liquid etc., consumers should check whether foreign substances such as toys are not present in the mouth before giving children baby food or milk.
2) Before buying toys, consumers should check the intended age for them and should refrain from buying them for children who do not reach the intended ages. After buying toys, consumers should check the reach of younger children in advance and keep the above-mentioned toys, especially objects 6 to 20 mm in size, out of the reach of younger children.

(3) Collection and Sharing of Information toward Safety Improvement

The Consumer Affairs Agency should ensure that other administrative bodies, toy-related enterprises, and consumers collect and accumulate and widely share among parties involved information including the age of children in months, type, size, shape, and intended age for a toy with which an accident occurred, conformity to standards or international standards for the safety of toys such as the ST Standard, store of the toy, owner of the toy, and action taken so that they can gain a detailed understanding of situations in which accidents such as aspiration and choking have occurred and types of toys that have caused accidents and take specific actions required to prevent recurrence of accidents. In addition, it is desirable to collect and accumulate medical images such as CT images to the extent possible.

(4) Dissemination for Preventing Serious Disease

The Consumer Affairs Agency should work with the Fire and Disaster Management Agency to encourage consumers to learn appropriate actions to be taken in case of airway obstruction (back blow maneuver, chest thrust maneuver, and Heimlich maneuver) from experts at their local fire departments or local Japan Red Cross Society branches.

Report

Preface

The Consumer Safety Investigation Commission[1] (hereinafter referred to as "the Investigation Commission") is tasked with investigating the cause of an actual or potential consumer-related incident involving bodily harm and the source of harm from such an incident and recommending that the Prime Minister create policies or take measures in order to prevent instances of the same or similar type of actual or potential accident from recurring or increasing or reduce harm or stating an opinion to the Prime Minister or the head of the relevant administrative organs about the policies or measures that should be taken in order to prevent instances of the same or similar type of actual or potential accident from recurring or increasing or reduce harm, under the Consumer Safety Act.

Actual or potential accidents that can be subject to an investigation by the Investigation Commission are actual or potential consumer-related incidents involving bodily harm, except actual or potential accidents which are subject to an investigation by the Japan Transport Safety Board. They include accidents in a wide range of consumer affairs familiar to consumers, such as food, products, facilities, and services. Among such accidents, the Investigation Commission is to select an actual or potential accident for which the Investigation Commission finds it necessary to clarify the cause or source in order to prevent instances of bodily harm from occurring or increasing and to investigate the cause or source of the actual or potential accident.

The Investigation Commission carries out an investigation into the cause or source of the selected actual or potential accident (hereinafter referred to as "Investigation by the Commission"). However, if another administrative organ has already carried out an investigation or monitoring, which can be used for necessary investigation into the cause or potential, the Investigation Commission is to investigate the cause or source of the relevant actual or potential accident using the results of the investigation. This refers to an "Evaluation of the Results of an Investigation or Monitoring by Another Administrative Organ and Entity (hereinafter referred to as an "Evaluation)."

This Evaluation is carried out by the Investigation Commission with a view to ensuring consumer safety and may be different in purpose or perspective from an Investigation or

[1] Established in the Consumer Affairs Agency on October 1, 2012 with the revision of the Consumer Safety Act (Act No. 50 of June 5, 2009).

Monitoring by Another Administrative Organ or Entity. Therefore, if the Investigation Commission considers that particulars necessary to investigate the cause or source of the relevant actual or potential accident with a view to ensuring consumer safety need to be further elucidated based on the results of an Evaluation, the Investigation Commission states an opinion about the investigation into the cause or source to administrative organs or entities responsible for administrative processes for an Investigation or Monitoring, as needed. If further investigation is considered necessary, the Investigation Commission is to carry out an investigation by the Investigation Commission in order to elucidate these necessary particulars.

The above-mentioned investigation by the Investigation Commission and Evaluation are collectively referred to as an Investigation and Evaluation. An outline of the process of an Investigation and Evaluation is provided in the figure on the next page.

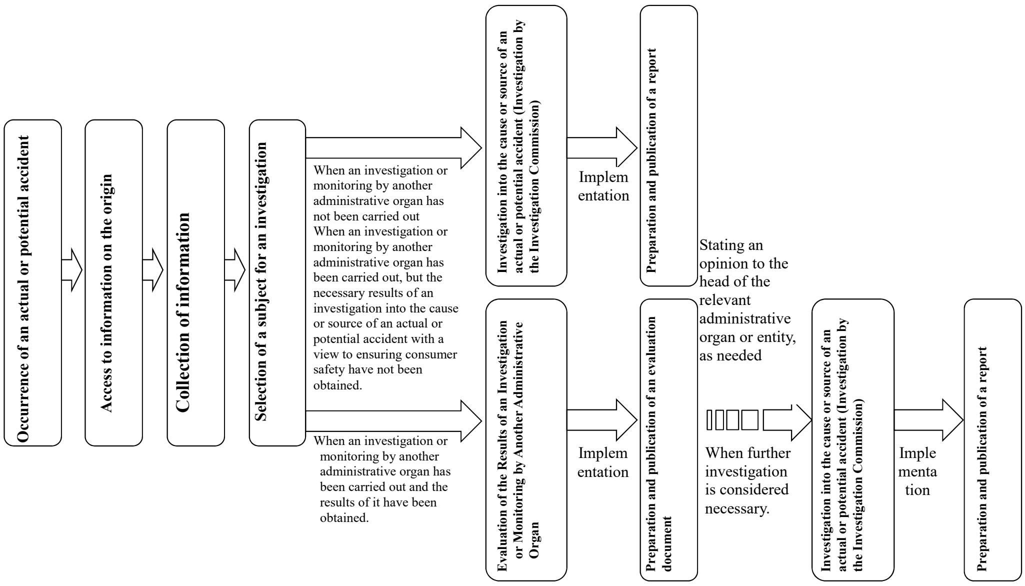


Figure Flow of investigations or evaluations by the Consumer Safety Investigation Commission

<Articles referenced>

○Consumer Safety Act (Act No. 50 of 2009) [excerpt]

(Investigations into the Cause or Source of an Actual or Potential Accident)

Article 23 (1) If the Investigation Commission finds it to be necessary to clarify the Cause or Source of an Actual or Potential Accident Involving Bodily Harm in order to prevent instances of bodily harm from occurring or increasing (meaning to prevent instances of harm from an Actual or Potential Accident Involving Bodily Harm from increasing or to prevent the same or a similar type of Actual or Potential Accident Involving Bodily Harm from occurring; hereinafter the same applies), it is to Investigate the Cause or Source of the actual or potential accident; provided, however, that this does not apply if the necessary results have been or are expected to be obtained from an Investigation or Monitoring by Another Administrative Organ or Entity into an Actual or Potential Accident Involving Bodily Harm though which the Investigation Commission considers the Cause or Source of the actual or potential accident can be clarified with a view of Ensuring Consumer Safety.

(2) to (5) (skipped)

(Evaluation of the Results of an Investigation or Monitoring by Another Administrative Organ or Entity)

Article 24 (1) If an Actual or Potential Accident Involving Bodily Harm has occurred and the Investigation Commission finds it necessary to clarify the Cause or Source of an Actual or Potential Accident Involving Bodily Harm in order to prevent instances of bodily harm from occurring or increasing, it must Evaluate the results of any Investigation of Monitoring by Another Administrative Organ or Entity as provided in the proviso to paragraph (1) of the preceding Article, once these results have been obtained.

(2) If as a result of the Evaluation referred to in preceding paragraph, the Investigation Commission finds it necessary to do so with a view of Ensuring Consumer Safety, it may state its opinion to the head of the administrative organ in charge of the administrative processes involved in the Investigation or Monitoring by the Other Administrative Organ or Entity, with regard to its clarification of the Cause or Source of the Actual or Potential Accident Involving Bodily Harm.

(3) If, as a result of the Evaluation referred to in paragraph (1), the Investigation Commission finds it necessary to implement an investigation in order to clarify the Cause or Source of an Actual or Potential Accident Involving Bodily Harm with a view to Ensuring Consumer Safety, the Investigation Commission is to Investigate the Cause or Source of that actual or potential accident.

(4) The head of an administrative organ in charge of the administrative processes involved in the Investigation or Monitoring by Another Administrative Organ or Entity referred to in paragraph (1) may hear the Investigation Commission’s opinion with regard to the Investigation or Monitoring by the Other Administrative Organ or Entity.

The definitions of terms used for description in the text throughout this report are as follows:

○Aspiration

Accidental entrance of food or foreign matter into the trachea for any reason. Commonly presenting with “choking,” “coughing,” “difficulty in breathing,” and other symptoms.

○Accidental ingestion

Accidental ingestion of foreign matter, which then reaches the digestive organs below the esophagus.

○Almost accidental ingestion

Accidental placement of foreign matter in the mouth.

○Airway obstruction

Obstruction of the airway by food or foreign matter.

○Asphyxiation

Lack of oxygen (hypoxia) resulting from airway obstruction and associated inability to breathe. Commonly presenting with “placing the hands on the throat (representing a choke sign),” “cyanosis (a condition in which the skin turns a color between blue or purple and dark brown),” and other symptoms.

1. Summary of Accidents

1.1 Filing for an Investigation into the Cause or Source

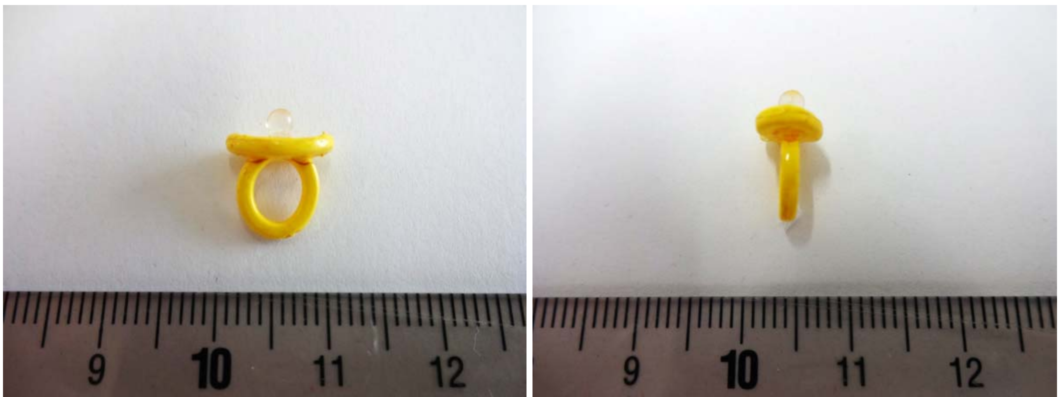
The Investigation Commission received a filing for the investigation into the cause or source of an accident in which a 9-month-old boy choked on a toy (with a diameter of approximately 10 mm) of his sibling (a young child) and died.
This filing prompted the Investigation Commission to decide to collect information on airway obstruction accidents due to toys in infants.

1.2 Description of the Accident

(1) Case Filed

While eating baby food, a 9-month-old boy suddenly turned pale and gradually got exhausted. Although a family member gave back blows or rescue breathing to him, emergency staff, arriving at 10 to 15 minutes, confirmed cardiopulmonary arrest. Emergency staff examined his mouth and discovered a pacifier-shaped toy for dolls (Picture 1; hereinafter referred to as a “pacifier-shaped toy”). The toy was a toy of his older brother/sister (young children), but it remains unclear when and where the boy put it in his mouth.

After being transferred to a hospital, the boy received intensive care such as mechanical ventilation and therapeutic hypothermia with a diagnosis of hypoxia due to choking, but died approximately three months later.



Picture 1. Pacifier-shaped toy[2]

[2] Taken by the Investigation Commission.

(2) Other Cases

According to the "Injury Alert"[3], which the Committee of Children Living Environment Improvement of the Public Interest Corporation Japan Pediatric Society (hereinafter referred to as "Japan Pediatric Society") makes publicly available on the Society's website, seven cases of airway obstruction accidents due to toys have been reported during the period of approximately 10 years from March 2008 to September 2017[4]. Among them, an overview of three cases of accidents (fatal accidents) is provided.

It should be noted that the above seven reports are limited to information on accidents which was collected by pediatricians through voluntary efforts and which was permitted by the family, etc. to be posted on this website etc. It should be therefore noted that the number does not accurately reflect the number of accidents occurring over 10 years.

(a) Case 1

When a 3-years-and-9-month-old boy was playing at home with two bouncy balls (Photo 2) of 35 mm in diameter in his mouth, he inhaled one through the mouth and was suffocated (he ejected the other from the mouth). His mother tried to take out it with her fingers put in his mouth, but she couldn't. She called an ambulance. At 37 minutes after suffocation, the boy was transferred to an emergency medical center with the bouncy ball stuck in the throat, but subsequently died.

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[3] In 2008, with a view to preventing the recurrence of severe injuries, the Committee of Children Living Environment Improvement of the Public Interest Corporation Japan Pediatric Society included the section of "Injury Alert" in the Journal of the Japan Pediatric Society and website for the Society to post cases that describe the fact of injuries as accurately as possible.

[4] In the accident information data bank, there were two reported cases of airway obstruction accidents due to toys in infants (identified from a search with the age group of victims set as 0 to 10 years of age, the description of injuries as "choking," "decreased skin sensation," "respiratory disorder," and "other injuries and symptoms," the target product as "toys," "playthings," "bouncing balls," "marbles," and "balls (excluding ball games, baseball, and eye balls)" between April 2010 and September 2017. In addition, according to the MHLW's hospital monitors' report on household product-related health damages in FY2015 (hereinafter referred to as "Hospital Monitors' Report"), four cases classified as "accidental ingestion of a toy" that were deemed to represent airway obstruction accidents due to toys based on the description of injuries, etc. were reported. It should be noted that information on one case of accident may be redundantly registered both in the accident information data bank and in the Hospital Monitors' Report.

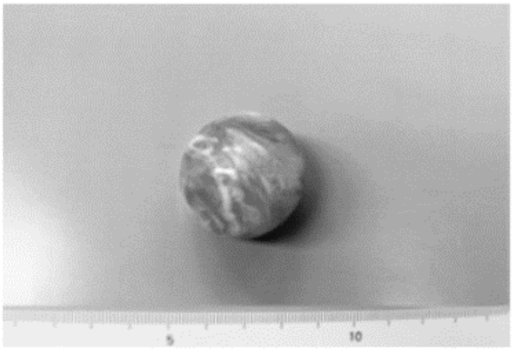

Photo 2. Bouncy ball inhaled by the boy[5]

(b) Case 2

A 1-year-and-8-month-old girl swallowed and choked on a hard plastic ball 20 mm in diameter (Photo 3) at home that was gotten from a pharmacy in the daytime on the day, while her family members took their eyes off her.

After dinner, her older brother found her choking on the ball while she was playing alone under the dining table. When he heard her gagging and looked at her, she presented with labored breathing.[6] It was unknown when the ball was placed on the floor. Her mother tried to take it out with her fingers put in the girl's mouth, but she couldn't, because the ball was stuck in the upper pharynx. She was transferred to a hospital by ambulance, but subsequently died.

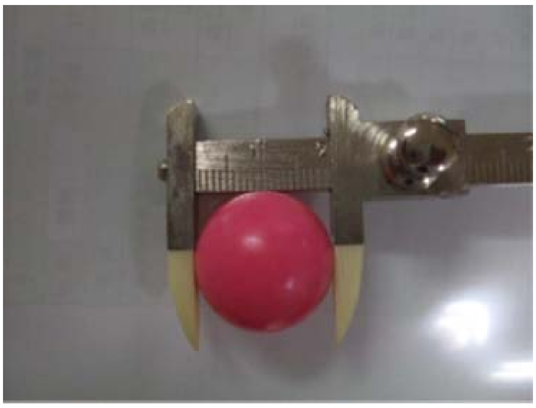

Photo 3. Hard plastic ball of 20 mm in diameter[7]

[5] Source: Japan Pediatric Society, "Injury Alert No.3 – Choking due to bouncy balls" (in Japanese) (https://www.jpeds.or.jp/uploads/files/injuryalert/0003.pdf, accessed on October 19, 2017)

[6] Breathing using respiratory muscles that are not used for breathing at rest (from the website of the Japan Association for Acute Medicine).

[7] Source: Japan Pediatric Society "Injury Alert No.3 – Similar cases of choking due to bouncy balls" (in Japanese) (https://www.jpeds.or.jp/uploads/files/injuryalert/0003_example.pdf, accessed on October 19, 2017)

(c) Case 3

A 2-year-old girl aspirated a wooden strawberry-shaped toy of 35 mm in diameter at the center) for playing house at home (the tip part of the object which could be divided into two pieces with a hook and loop fastener) (Photos 4 and 5).

Photo 4. Wooden toy[8]

Photo 5. Tip part of the toy aspirated[9]

Her mother tried to scrape the toy with her fingers put in the girl's mouth, but it was tucked further in the back. She immediately gave back blows to the girl, but couldn't take it out and called an ambulance. The girl suffered cardiopulmonary arrest during transfer, arrived at a hospital 18 minutes after foreign matter aspiration, and received treatment; however, she died about six months later. Photo 6 is an MRI scan of the head taken at 72 hours after hospitalization, showing that foreign matter was present in the upper pharynx (inside the circle).

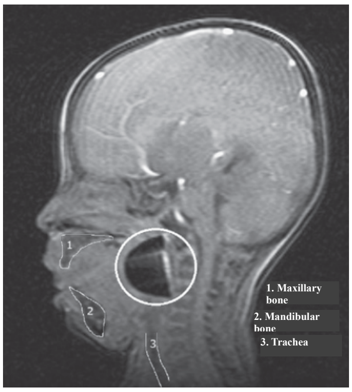

Photo 6. MRI scan taken at 72 hours after hospitalization[10]

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[8] Source: Japan Pediatric Society "Injury Alert No.47 – Photo 1 of choking due to aspiration of a wooden toy" (in Japanese) (https://www.jpeds.or.jp/uploads/files/injuryalert/0047.pdf, accessed on October 19, 2017)

[9] Source: Japan Pediatric Society "Injury Alert No.47 – Photo 2 of choking due to aspiration of a wooden toy" (in Japanese) (https://www.jpeds.or.jp/uploads/files/injuryalert/0047.pdf, accessed on October 19, 2017)

2. Progression of the Investigation into the Cause or Source

2.1 Reason for Selection

The Investigation Commission selected airway obstruction accidents due to toys in infants as subjects of an investigation into the cause or source with an emphasis on the following elements in accordance with "Guidelines for Selection of Subjects of Investigations or Evaluations" (Consumer Safety Investigation Commission Decision of October 3, 2012).

- Toys have a highly "public nature," because they are widely used in the daily life of infants.
- "Extent of harm" is significant, because fatal accidents due to airway obstruction have occurred.
- Mainly infants, individuals who require special consideration from the viewpoint of ensuring consumer safety, suffer or may suffer harm ("Focus on those who require consideration").

It should be noted that there are many toys that infants potentially aspirate or accidentally ingest, with their shapes or functions varying widely, and measures for prevention of recurrence may also vary with subjects. Therefore, the subjects of this investigation were limited to "toys" listed in the "Japan Standard Commodity Classification"[11] to conduct an investigation in depth to the extent possible.

2.2 Investigation Organization

The Investigation Commission designated Koji Kitamura, who specialized in human engineering (senior researcher, Artificial Intelligence Research Center, National Institute of Advanced Industrial Science and Technology), Itsuko Horiguchi, who specialized in

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[10] Source: Japan Pediatric Society "Injury Alert No.47 – Photo 3 of choking due to aspiration of a wooden toy" (in Japanese) (https://www.jpeds.or.jp/uploads/files/injuryalert/0047.pdf, accessed on October 19, 2017)

[11] The Japan Standard Commodity Classification (JSCC) was established by the government (Ministry of Internal Affairs and Communications) in March 1950 as a standard for indicating results from statistical research by product (revised in October 2013).

public health (associate professor, Center for Public Relations Strategy, Nagasaki University), and Yukihiro Michiwaki, who specialized in oral surgical management and rehabilitation of oral dysfunction (Director, Oral Surgery Division, Musashino Red Cross Hospital) as expert members assigned the investigation of this type of accidents and conducted deliberations with the Accident Investigation Subcommittee for Products, etc.

2.3 History of the Investigation

2016

November 18: Airway obstruction accidents due to toys in infants selected as subjects of Investigations and Evaluations at the 51st meeting of the Investigation Commission.

December 8: An investigation plan discussed at the 3rd meeting of the Accident Investigation Subcommittee for Products, etc. under the Investigation Commission.

2017

January 19: An investigation plan discussed at the 4th meeting of the Accident Investigation Subcommittee for Products, etc. under the Investigation Commission.

March 7: A report provided on the progression of the investigation at the 6th meeting of the Accident Investigation Subcommittee for Products, etc. under the Investigation Commission.

March 14: A report provided on the progression of the investigation at the 55th meeting of the Investigation Commission.

April 14: A report provided on the progression of the investigation at the 7th meeting of the Accident Investigation Subcommittee for Products, etc. under the Investigation Commission.

May 18: A report provided on the progression of the investigation at the 8th meeting of the Accident Investigation Subcommittee for Products, etc. under the Investigation Commission.

June 20: A report provided on the progression of the investigation at the 9th meeting of the Accident Investigation Subcommittee for Products, etc. under the Investigation Commission.

June 30: A report provided on the progression of the investigation at the 58th meeting of the Investigation Commission.

July 11: A report provided on the progression of the investigation at the 10th meeting of the Accident Investigation Subcommittee for Products, etc. under the Investigation Commission.

August 18: A report provided on the progression of the investigation at the 11th meeting of the Accident Investigation Subcommittee for Products, etc. under the Investigation Commission.

August 25: A proposed progression report and a draft investigation report discussed at the 60th meeting of the Investigation Commission.

September 19: A proposed progression report and a draft investigation report discussed at the 12th meeting of the Accident Investigation Subcommittee for Products, etc. under the Investigation Commission.

September 22: A proposed progression report and a draft investigation report discussed at the 61st meeting of the Investigation Commission.

October 24: A progression report discussed and finalized at 62nd meeting of the Investigation Commission.

November 16: A draft investigation report discussed at the 13th meeting of the Accident Investigation Subcommittee for Products, etc. under the Investigation Commission.

November 20: An investigation report discussed and finalized at the 63rd meeting of the Investigation Commission.

2.4 Hearing of Opinions from Persons Linked to the Cause or Source

Opinions were heard from persons linked to the cause or source.[12]

[12] A person linked to the cause or source (Paragraph 2 (i), Article 23 of the Consumer Safety Act) refers to any person found to have a connection to the cause or source of the actual or potential accident, regardless of the person’s responsibility.

3. Basic Information

3.1 Basic Information on Airway Obstruction and Asphyxiation

An airway obstruction accident due to a toy is an accident in which a toy present in the mouth for any reason enters the pharynx secondary to an unexpected dropping or an attempt at swallowing, but cannot be swallowed or gotten back to the mouth, to block the pharynx or larynx.
This section provides an overview of asphyxiation and related organs.

3.1.1 What is Asphyxiation?

We inhale air through the nose or mouth into the lungs, in which oxygen in air is taken into blood. This process is called respiration and the nose (nasal cavity), mouth (oral cavity), throat (pharynx and larynx), and trachea, which are all passages of air, are collectively called the airway.[13] Asphyxiation is a condition of lack of oxygen (hypoxia) resulting from airway obstruction and associated inability to breathe.

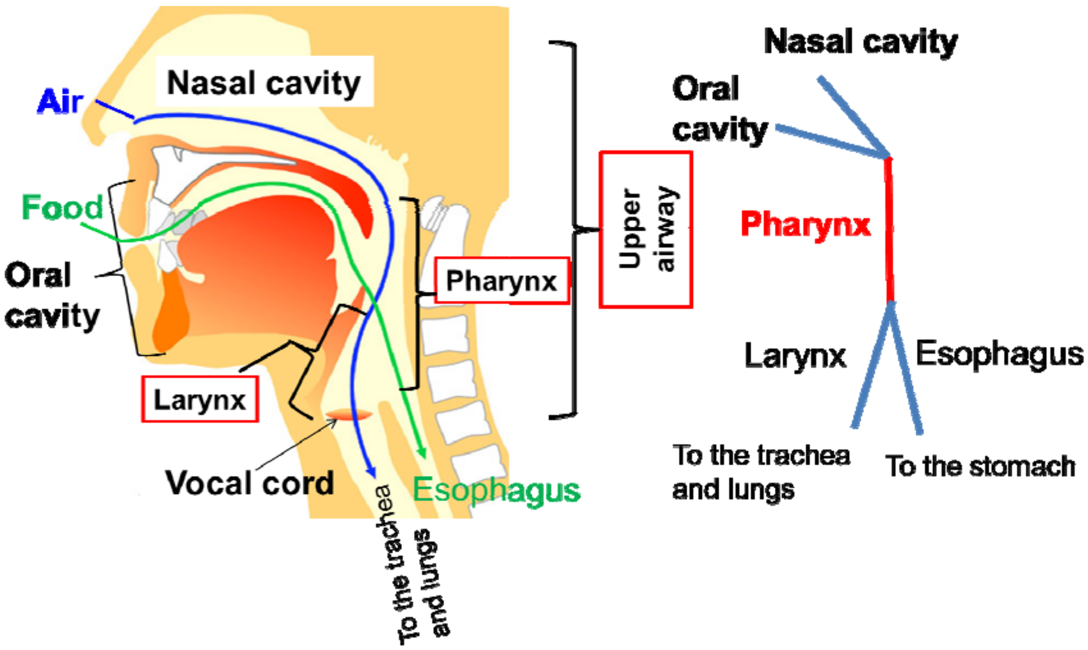

Figure 1. Organs related to asphyxiation (left) and a schematic diagram of mutual relationships of the organs (right)

[13] The portion of the airway above the vocal cords is called the upper airway and the portion below the vocal cords is called the lower airway. The nose, mouth, and throat are part of the upper airway.

The pharynx is a tube-like structure that is Y-shaped at both its upper and lower ends (on the right in Figure 1, represented by the red line) and opens into the nasal and oral cavities at its upper end and into the esophagus and larynx at its lower end. Air from the nasal cavity and food from the mouth both enter the pharynx, which then divides into two separate branches. Air passes through the larynx and trachea into the lungs and food passes through the esophagus into the stomach. The pharynx, which is a common passage for both air and food (a portion of the digestive tract), may be thus blocked by food, etc. to cause airway obstruction, leading to inability to breathe. A condition of lack of oxygen due to obstruction of the pharynx is called pharyngeal obstruction-type asphyxiation.

The larynx is a passage of air and opens into the pharynx at its upper end and into the trachea at its lower end. The vocal cords form the boundary between the trachea and larynx. The gap formed by the vocal cords is called the glottis, through which expired air and inspired air come and go. Blockage of the vocal cords by food or foreign matter entering the larynx without lodging in the pharynx can also cause airway obstruction, leading to an inability to breathe, and therefore asphyxiation. A condition of lack of oxygen due to obstruction of the larynx is called laryngeal obstruction-type asphyxiation.

3.1.2 Suffocation and Life-saving Support

Our face turns bluish-purple (cyanosis) at three to four minutes after suffocation and breathing stops at about five to six minutes to cause loss of consciousness. Subsequently, the heart stops beating, to cause cerebral damage, leading to brain death at 15 minutes or more (Figure 2)[14].

[14] The times showing the course after choking are only as a guide.

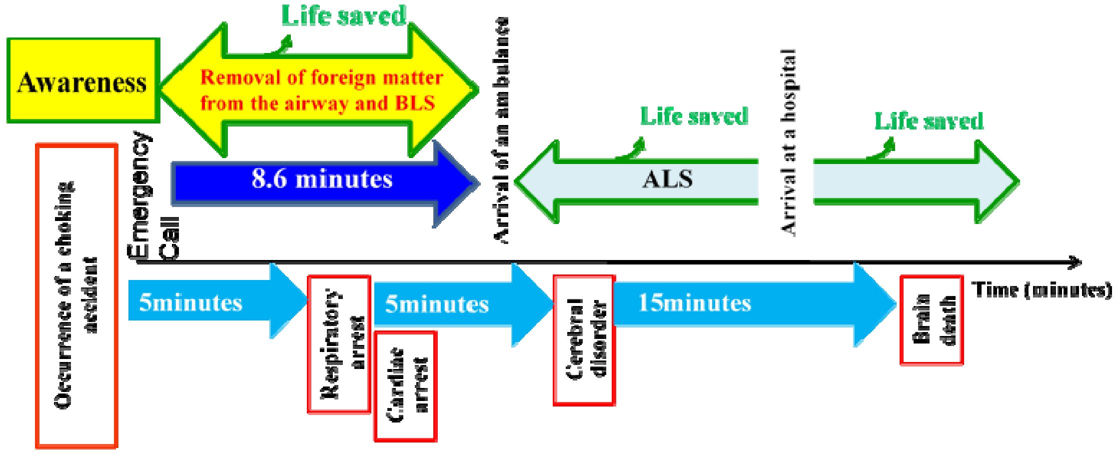

Figure 2. Course after the occurrence of a choking accident and life-saving measures[15]

Because infants are less resistant to oxygen deficiency than adults, they are more likely to develop serious hypoxia.

It has been reported that the average time from the receipt of a call for an ambulance to the arrival of an ambulance at the scene is 8.6 minutes.[16] If anyone on the scene stands by doing nothing before the arrival of emergency medical services, respiratory arrest and cardiac arrest may occur during the interval of 8.6 minutes. Thus, the development of airway obstruction leads to the occurrence of serious disease in a short time, which creates a need for prompt intervention. Effective methods for removing foreign matter include back blows[17] and chest thrusts[18], as well as the Heimlich maneuver (abdominal thrust)[19] in infants aged one year or older.

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[15] Basic life support is first aid provided by bystanders to a victim suffering from choking until the victim is taken over by an emergency response team or a physician. It involves assessing the total body of the victim, checking for response (consciousness), calling for an ambulance, as well as making an attempt to recover spontaneous blood circulation with airway control, artificial respiration, and cardiac massage. In cardiopulmonary resuscitation, the initiation of chest compression as early as possible even without using any specialized instruments or drugs determines prognosis. Advanced life support is a cardiopulmonary resuscitation procedure that follows basic life support and is provided by a physician or adequately trained nurse or emergency medical technician with assistive devices for medical use or drugs.

[16] Fire and Disaster Management Agency "2016 edition of the current state of first-aid and rescue operations" (in Japanese) (http://www.fdma.go.jp/neuter/topics/kyukyukyujo_genkyo/h28/01_kyukyu.pdf, accessed on October 19, 2017)

[17] While supporting the victim's body in one hand with the victim's chin securely supported with the palm, blows should be given to the victim's back with the base of the flat of the other hand.

[18] While supporting the victim's body in one hand with the back of the victim's head securely supported with the palm, compression should be applied to the victim's chest in the same manner as chest compression for cardiopulmonary resuscitation.

[19] The arms should be put around the victim from behind and one fisted hand should be placed below the pit of the victim's stomach. The fist should be held with the other hand and upward pressure should be applied to the victim's abdomen with both hands. This maneuver should not be used in pregnant women or infants (up to the age of 12 months) because of high risk of complications such as visceral injury.

3.2 Guidelines for Child Safety and International Standards for Toys

Guidelines for child safety include ISO/IEC Guide 50 (hereinafter referred to as "Guide 50"). Guide 50 provides guidance for developing safety standards for products[20] that children use or with which they are likely to come into contact[21] and addresses toys as well as hazards surrounding children[22] and countermeasures against such hazards. ISO 8124 are safety standards that define safety standards or test methods for toys and follow the concept of Guide 50.

3.2.1 ISO/IEC Guide 50

From the standpoint of what kinds of risks of bodily injuries associated with development or vigorous curiosity of children and other factors[23] are possible and how such risks should be addressed, Guide 50 presents a variety of hazards.

For example, in the context of airway obstruction accidents, Clause 7.7.1 "Small objects" of Guide 50 states that "Small objects and parts of products present potentially serious hazards, especially to toddlers and young children. Small objects can enter the airway, trachea, and esophagus, blocking airflow to the lungs. Rounded (e.g., spherical) objects can block the airway at the back of the mouth, also causing asphyxia. Conforming objects such as latex balloons are especially hazardous."

In addition, Guide 50 describes strategies to avoid or reduce risks due to small objects, including "eliminating small parts, in particular, shapes such as spheres and cones should be avoided" and "applying secondary prevention strategies such as providing continuous air passages, so that if the part is inhaled the child can still breathe."

3.2.2 ISO 8124

For ISO 8124, the matters related to small parts included in Guide 50 are specified in Part 1.[24]

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[20] Including manufactured articles, including their packaging, processes, structures, installations, services, built environments, or a combination of any of these.
[21] The first edition was issued in 1987 and the current third edition was issued in December 2014. The third edition has been established as a JIS standard (JIS Z8050:2016) in Japan.
[22] A potential source of harm, as per the definition in JIS Z8050:2016.
[23] A combination of the probability of occurrence of harm and the severity of that harm, as per the definition in JIS Z8050:2016.
[24] The first edition of Part 1 was issued in 2000 and the current fourth edition was issued in 2014.

3.3 National Laws or Regulations on Toys

In Japan, there are no established laws or regulations for the prevention of airway obstruction accidents due to toys.

3.3.1 Toys Safety Standard and Safety Toy Mark Program

The Japan Toy Association (hereinafter referred to as “the JTA”), a trade association, manages and operates Toys Safety Standard and Safety Toy Mark Program (commonly known as “ST Standard and ST Mark Program,” hereinafter referred to as “ST Standard” and “ST Mark Program,” respectively) to enhance the safety of toys that are commercially available in Japan.[25]

The ST Standard is the toys’ safety standard developed by the JTA and is available to everyone in developing toys. The JTA operates the ST Mark Program using the ST Standard.

The ST Mark Program is a program in which the JTA enters into a ST Mark License Agreement with a business proprietor who manufactures, imports, or sells toys, conducts a ST Standard Conformity Test, and permits conforming toys to bear the ST Mark.

A business proprietor who manufactures, imports, or sells toys requests a testing body designated by the JTA (hereinafter referred to as “a designated testing body”) to conduct a ST Standard Conformity Test for toys handled by the business proprietor if the business proprietor wants such toys to bear the ST Mark (Figure 3). If toys are considered as conforming to requirements and test methods specified in the ST Standard, they can be released as products with the ST Mark borne on them or their package.

In entering into the ST Mark License Agreement, business proprietors who manufacture, import, or sell toys are required to join Mutual Aid Project and indemnified by the JTA for damages paid by the business proprietors to victims by reason of accidents caused by a defect of toys bearing the ST Mark (Figure 4).

[25] The ST Standard and ST Mark Program were established in 1971 and the ST Standard has been revised, as needed, by reference to information on accidents and revisions of domestic and overseas regulations and international standards. The current standard, ST-2016, was issued in April 2016.

Figure 3. ST Mark[26]

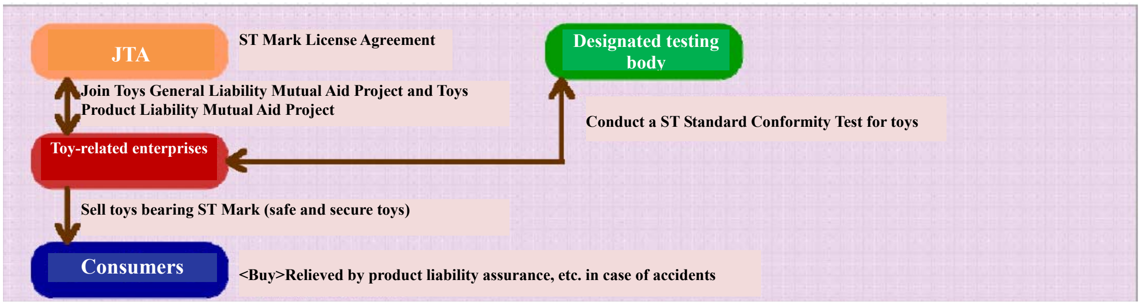

Figure 4. ST Mark Program[27]

3.3.2 Overview of ST Standard

ST-2016, the current ST Standard, consists of three parts and the matters related to airway obstruction accidents are specified in Part 1.[28]

[26] Source: Japan Toy Association "Business Information" (in Japanese) (http://www.toys.or.jp/pdf/jta_business_info.pdf, accessed on October 19, 2017).
[27] Source: Japan Toy Association "Business Information" (in Japanese) (http://www.toys.or.jp/pdf/jta_business_info.pdf, accessed on October 19, 2017)
[28] On the occasion of transition to ST-2012, a decision was made to ensure compliance with ISO 8124.

Table 1. Overview of Part 1 of the ST Standard

Organization	Description	Hazards to Prevent
Part 1 Mechanical and physical properties	Standards for ensuring the safety related to shape or strength of toys	"Accidental ingestion" (Small parts, mouth-actuated toys, expanding materials, small strong magnets, buttons, and coin-shaped batteries) "Choking" (toys/parts that can be settled in the mouth, thin films, small bags, helmets) "Hanging" (strings) "Cuts" (sharp edges, glasses, catches) "Stabs" (sharp tips, wires) "Clamp wounds" (hinges, toys with folding mechanisms, driving mechanisms, springs) Others, including "fall," "damage to eyes," hearing impairment," and "drowning"

Prepared by the Investigation Commission based on the data provided by the Japan Toy Association (December 9, 2008)

Part 1 specifies requirements and test methods for toys intended for use by children in various age groups from birth to the age of 14 years.

The requirements specified include those for materials of toys, small parts[29], shape, size, and strength of certain toys[30], edges, points, projections, stability or load, and other enclosures.

The requirements and test methods may vary according to the age; for example, for small parts under which the toys intended for children under 36 months and the toys intended for children 36 months and over are separated. Designated testing bodies are to apply the requirements and test methods appropriate for the intended age indicated, but are to apply tests providing the most stringent requirements for two or more age groups if the intended age indicated by business proprietors who manufacture, import, or sell toys extends across two or more age groups.

The ST Standard specifies the items to be indicated on toys and requires that the name, trademark, and address of a business proprietor who manufactures, imports, or sells toys, and various precautionary statements, as well as intended ages, if determined, should be indicated. Toys on which intended ages are not indicated are handled as those intended for all ages up to 14 years of age.

[29] Although Section 4.4 of the ST Standard is the section "small part," no clear definition of small parts is established. This standard handles solids that fit entirely in the test device (small parts cylinder shown in Figure 5) as components of toys (small parts) that children under three years potentially accidentally ingest.

[30] Specific toys with individual sections established include "squeeze toys, rattles, and certain other toys" (Section 4.5.1.2 of the ST Standard), "small balls" (Section 4.5.2 of the ST Standard), and "pompoms" (Section 4.5.3 of the ST Standard).

In addition, the toys required to carry appropriate warning statements shall carry appropriate warnings that are clear and legible (Section 7.1.2 of the ST Standard).

3.3.3 ST Standard Relevant to Airway Obstruction Accidents

Examples of the requirements, test methods, and markings specified in Part 1 which are potentially relevant to airway obstruction accidents in infants are shown below in (1) to (3)[31].

(1) Requirements and Test Methods for Small Parts

(a) Requirements (Section 4.4 "Small parts" of the ST Standard)

As described earlier, the requirements for small parts are presented separately for the toys intended for children under 36 months and the toys intended for children 36 months and over.

Toys intended for children under 36 months, removable components thereof, and components liberated during testing in accordance with reasonably foreseeable abuse[32] tests[33] shall not fit entirely, whatever their orientation, into the small parts cylinder (Figure 5) when tested in accordance with the small parts test shown below in (b).

Toys and toys containing removable components, intended for children 36 months and over, which fit entirely in the small parts cylinder when tested in accordance with the small part test shown below in (b), shall carry a warning as shown below in (3). In addition, this requirement also applies to toys intended for children under 96 months, which are liberated when tested in accordance with a drop test.

(b) Test method (Section 5.2 "Small parts test" of the ST Standard)

Place a toy, without compressing it and in any orientation, in the cylinder as shown in Figure 5. Repeat the procedure with any removable component of the toy and any component liberated after testing according to reasonably foreseeable

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[31] In addition to these examples, the requirements for "pre-school play figures," "hemispheric-shaped toys," and "pompoms" are established to address airway obstruction accidents and the requirements for small parts apply to "toys put in the mouth" and "small strong magnets."

[32] Defined as "use of a toy under conditions or for purposes not intended by the manufacturer, but which can happen, induced by the toy in combination with, or as a result of, common behavior in a child," according to Section 3.3 of the ST Standard.

[33] Defined as "to simulate situations in which possible damage can occur to a toy as a result of reasonably foreseeable abuse," according to Section 5.22.1 of ST Standard. See Section 5.22.2 and subsequent sections for details of tests.

abuse tests. Determine whether the toy or any removable component or liberated component fits entirely within the cylinder.

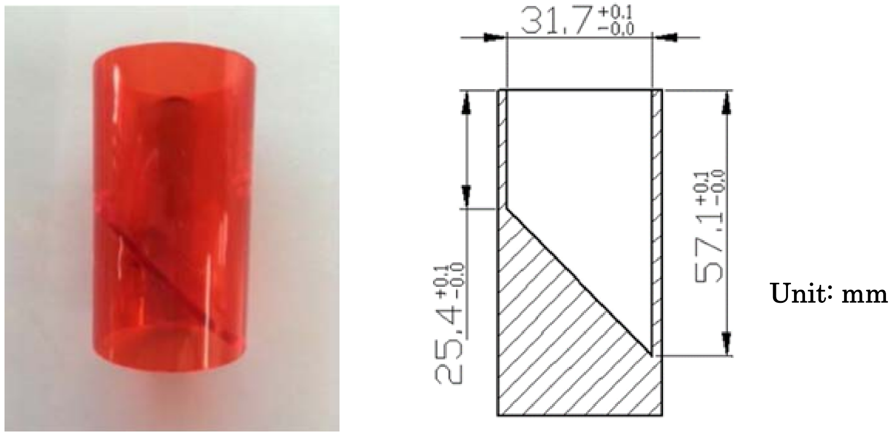


Figure 5: Small parts cylinder (Left: picture, right: drawing)

(2) Requirements and Test Methods for Small Balls

(a) Requirement (Section 4.5.2 “Small balls” of the ST Standard)

A small ball is any ball[34] that passes entirely through a template (Figure 6) when tested in accordance with the small balls test shown below in (b). Toys intended for children under 36 months shall not be small balls or contain removable small balls. Alternatively, small balls shall not be liberated when tested in accordance with reasonably foreseeable abuse tests such as a drop test.

Toys intended for children 36 months and over which are small balls or contain removable small balls shall carry a warning as shown below in (3). In addition, this requirement also applies to toys intended for children under 96 months that are liberated when tested in accordance with a drop test.

(b) Test method (Section 5.4 “Small balls test” of the ST Standard)

Position and clamp the test template C shown in Figure 6 so that the axis of the slot is essentially vertical and the slot is unobstructed at its top and bottom openings. Orientate the ball to be tested in a position that would most likely permit the entry of the ball through the slot in the test template. Place the ball in the slot so that the force on the toy is only the force due to its mass. Determine whether the ball passes

[34] According to Section 3.21 of ST Standard, “ball” is defined “a spherical, ovoid, or ellipsoidal object designed or intended to be thrown, hit, kicked, rolled, dropped, or bounced.”

entirely through the test template.

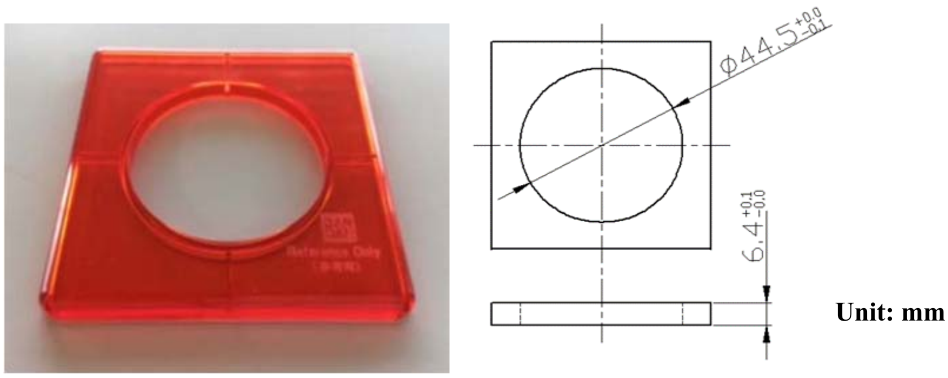


Figure 6. Test template C (Left: picture, right: drawing)

(3) Warning Statements

Section 4 “Requirements” of the ST Standard states that toys required to carry warnings shall carry appropriate warnings that are clear and legible. For example, for toys intended for children aged three years and older that are required to carry a warning in (1) and (2) or toys containing marbles, the toy or its packaging shall carry a warning statement that the toy is not suitable for children under three years.

3.4. Other Information Relevant to Airway Obstruction

3.4.1. Accidental Ingestion Checker[35]

Accidental Ingestion Checker is an educational tool that the Japan Family Planning Association[36] (hereinafter referred to as “the JFPA”) distributes for a fee to prevent accidental ingestion or choking in children. It is modeled on the maximum mouth opening and distance from the maxillary incisor to the deepest point in a 3-year-old child based on scientific values determined by measuring the oral cavity of infants and other means[37] (Figure 7). It is used in mothers’ classes[38], etc. sponsored by local

[35] Registered patent No. 3706795, registered trademark No. 5580046 and 5583495, registered design No. 1112380

[36] Founded in 1954. A private organization that has carried out activities in the education and promotion of family planning and maternal and child health (http://www.jfpa.or.jp/outline/).

[37] Social Welfare and Medical Service Corporation Child-rearing Support Foundation Grant Project “Report on investigation of accidents in infants/report on investigation of the volume of the oral cavity of infants” (in Japanese) (March 2002, Japan Family Planning Association)

governments. The JFPA encourages that objects that can hide in this Accidental Ingestion Checker should be placed at a height of at least one meter above the floor, because they are at risk of being ingested or causing choking (Figure 8).

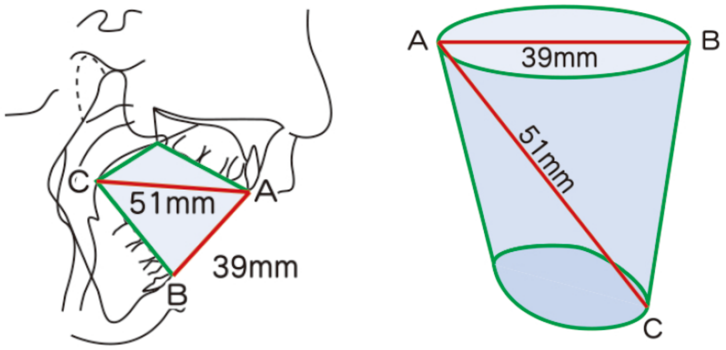


Figure 7. Child's oral cavity (Left) and Lateral view of Accidental Ingestion Checker (Right)[39]

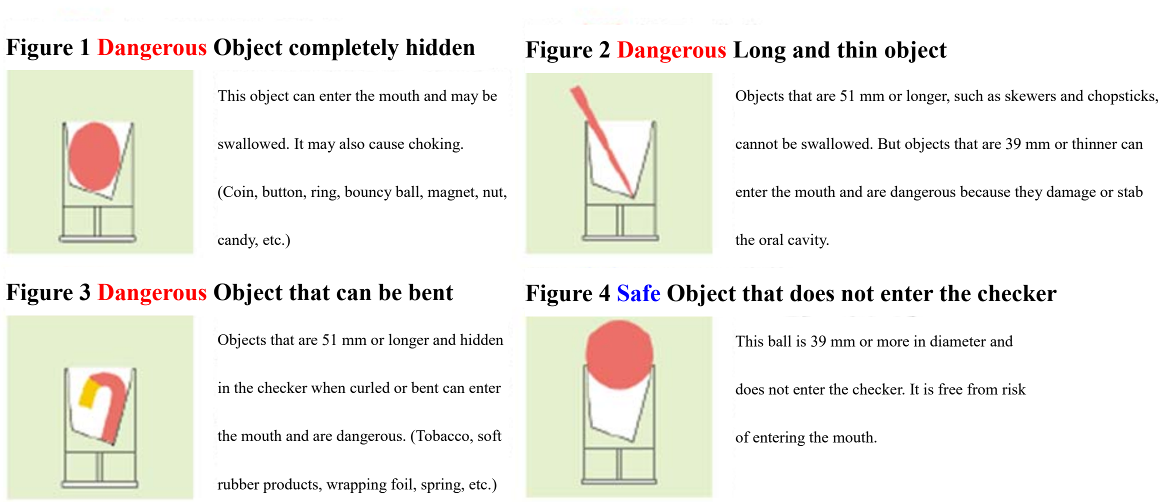


Figure 8. Use of Accidental Ingestion Checker[40]

3.4.2. Behavioral Characteristics of Children

(1) Children's Typical Exploration Strategies

[38] A class organized by the local government in which prenatal pregnant women, etc. participate to obtain knowledge on pregnancy, childbirth, and childcare. May be called "parenting class" or "mommy and daddy classes" in some local governments.

[39] Provided by the JFPA.

[40] Source: Japan Family Planning Association "How to use the Accidental Ingestion Checker" (http://www.jfpa.or.jp/mother_child/prevent/002.html, accessed on October 19, 2017)

JIS Z8050:2016 (Guide 50:2014) provides examples of children's typical exploration strategies. This report provides selected examples relevant to airway obstruction, as shown below (Table 2).

Table 2. Examples of children's typical exploration strategies [41]

Exploration strategies	Examples	Age peak	Illustrative examples
Mouthing	Biting, sucking, gnawing, chewing, licking	Birth to 3 years of age	Soother (or pacifier), wooden blocks, washcloths, clothing, food made of an inedible substance, teethers, toys, button/coin batteries (including coin-shaped lithium batteries), furniture, window sills (cross members located exteriorly or interiorly below a window, on which flower pots are often placed)
Insertion (body into object)	Children explore the objects within their environments, as well as their own bodies, by placing objects into their own body cavity.	2 to 6 years of age	Beads, stickers, peas, cotton buds, buttons, modeling clay, small parts from toys
Dropping	Dropping of objects begins extremely early in the life of a child. This type of exploration allows children to begin learning that objects continue to exist even when out of their sight and that they can have a certain level of control over the action of their parents or carers.	6 months to 3 years of age	Feeding utensil, pacifier, balls, small toys, toys that bounce or make noise when dropped.
Throwing	Children begin throwing whatever they can grasp. This strategy may provide information to children about weight, as well as being an exercise of motor skills and a statement of power.	1 to 4 years of age	Balls, Frisbees, plush toys, toys that fit in a child's hand, any object when angry or frustrated.

*Carer: A person who exercises responsibility, however temporarily, for an individual child' safety.

[Example] Parents, grandparents, siblings who have been given a limited responsibility over a child, other relatives, adult acquaintances, babysitters, teachers, child-minders, youth leaders, sports coaches, camp counselors, day care workers.

[41] Source: JIS Z8050:2016 Safety aspects – Guidelines for child safety in standards and other specifications.

(2) Reach of Children

There is an example that shows the range that children aged between one and three years can reach by age (Figure 9). This example is intended to recommend that the reach of a child should be checked and dangerous objects should be kept out of the reach.

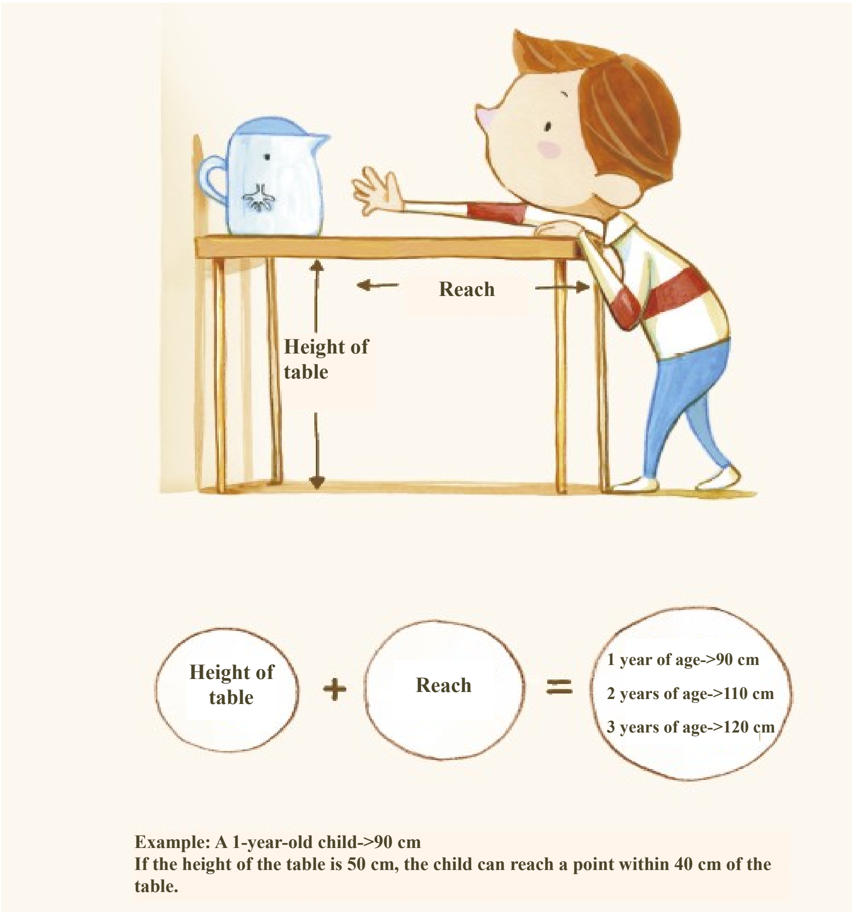


Figure 9. Reach of Children[42]

[42] Source: Specified non-profit corporation Safe Kids Japan "To prevent burns in children" (in Japanese) (http://safekidsjapan.org/wordpress/wp-content/uploads/2016/12/子どものやけどを予防するために-1.pdf, accessed on October 19, 2017)

4. Analysis 1 (Questionnaire and Interview)

The Investigation Commission recognized the need to collect more detailed information and comprehend the actual situation with regard to what age groups of children experience aspiration, even if not leading to airway obstruction accidents, and what types of toys are aspirated. Thus, the Investigation Commission conducted questionnaire surveys and interviews on the characteristics of toys that caused accidents, description of accidents, and first-aid responses among parents/guardians and educational/childcare facilities.[43] The Investigation Commission then conducted questionnaire surveys and interviews among toy-related enterprises to determine safety-related efforts made by enterprises. In addition, the Investigation Commission collected and analyzed data on emergency transportation.

It should be noted that "accidental ingestion" and "aspiration," as well as "airway obstruction," were included to collect a wide range of information, because airway obstruction accidents are caused by entrance of an object that is essentially not supposed to be put in the mouth into the mouth.

4.1. Questionnaire Survey among Parents/Guardians

A Web-based questionnaire survey was conducted among parent/guardians. Some of the parents/guardians who responded to the questionnaire survey were also interviewed to determine specific situations of the occurrence of accidents. In the questionnaire survey among parents/guardians, information was collected not only on toys but also small-sized stationery products that were also at hand and potentially put in the mouth by children, such as stickers and caps of pens.

4.1.1. Method of Survey

The subjects consisted of parents/guardians aged 18 years or older but younger than 80 years who lived in Japan and who had a child or grandchild aged between 0 and 6 years. The survey classified respondents into the following seven groups and planned to include approximately 300 respondents per group[44] during the survey from February 9

[43] Educational/childcare facilities include kindergartens, licensed daycare centers, certified childcare centers, and non-licensed daycare facilities.

[44] The questionnaire form was designed to ensure that a respondent was not included in two or more groups.

to February 20, 2017.

[Groups of respondents][45]

(a) Respondents responding that their child or grandchild “aspirated” a toy

(b) Respondents responding that their child or grandchild “accidentally ingested” a toy

(c) Respondents responding that their child or grandchild “almost accidentally ingested” a toy.

(d) Respondents responding that their child or grandchild “aspirated” a stationery product.

(e) Respondents responding that their child or grandchild “accidentally ingested” a stationery product.

(f) Respondents responding that their child or grandchild “almost accidentally ingested” a stationery product.

(g) Respondents responding that their child or grandchild “had never aspirated or accidentally ingested” a toy or stationery product.

4.1.2. Survey Results

(1) Sex and Age of Respondents to the Questionnaire

The number of respondents in each group and their sex and age are shown in Table 3. The respondents were well balanced between males and females and dominated by the age group of 31 to 40 years.

[45] For ease of understanding, “accidentally ingested” was defined as a foreign substance being accidentally ingested and entering the gastrointestine, “aspirated” as a foreign substance being accidentally ingested and entering the trachea, and “almost accidentally ingested” as a foreign substance being put in the mouth by a child in this questionnaire survey.

Table 3. Sex and age of respondents to the questionnaire

	Number of respondents	Males	Females	21 to 30 years of age	31 to 40 years of age	41 to 50 years of age	51 to 60 years of age	61 to 70 years of age	71 years of age or more
(a)	302	153	149	39	137	59	29	34	4
(b)	305	165	140	23	153	46	32	41	10
(c)	340	172	168	46	151	63	36	38	6
(d)	249	107	142	45	113	42	25	17	7
(e)	307	95	212	53	169	42	15	22	6
(f)	311	159	152	39	145	60	28	33	6
(g)	350	195	155	29	121	67	55	72	6
Total	2,164	1046	1118	274	989	379	220	257	45

Although information was also collected on small-sized stationery products such as stickers and caps of pens, as described in Section 4.1, this report shows the analysis with a focus on toys.

(2) Number of Accidents of Aspiration of Toys, Characteristics of Children, and Situation of the Occurrence of Accidents

A total of 302 parents/guardians of a child who had the experience of “aspirating” a toy were asked about the number of accidents of aspiration of toys over the previous one year. The results showed that 263 parents/guardians (87%) responded “at least one accident” and that 56 parents/guardians (18%) also responded “at least four accidents” It is highly probable that a certain number of aspiration accidents occur over a short time in households (Figure 10).
In addition, a question was asked about the age in month of children at the time of the occurrence of the most recent case of aspiration of toys and the results showed that the age category of ≥6 months and <1 year was the most common response (26% of the respondents). After the age of 1 year, accidents tend to decrease with the growth of children (Figure 11).

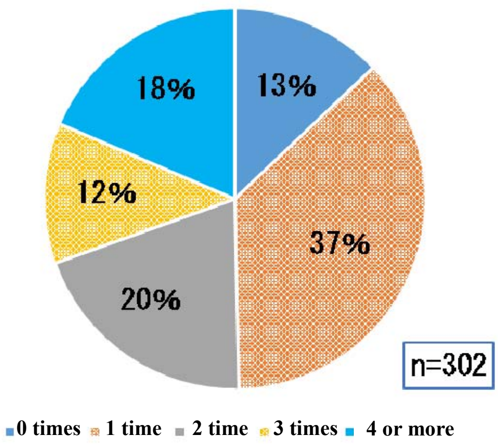


Figure 10. Number of accidents of aspiration of toys (over the last one year)

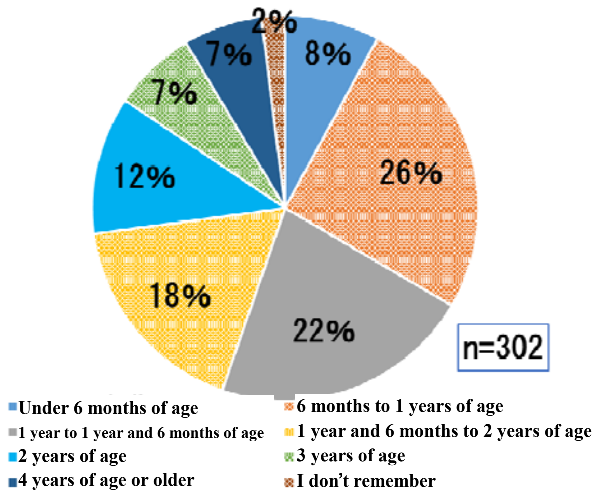


Figure 11. Age (in months) at the time of the most recent case of aspiration of toys

A total of 302 parents/guardians of a child who had the experience of “aspirating” a toy were asked about the situation of the child immediately before aspiration. The responses were as follows (Figure 12, multiple responses allowed):

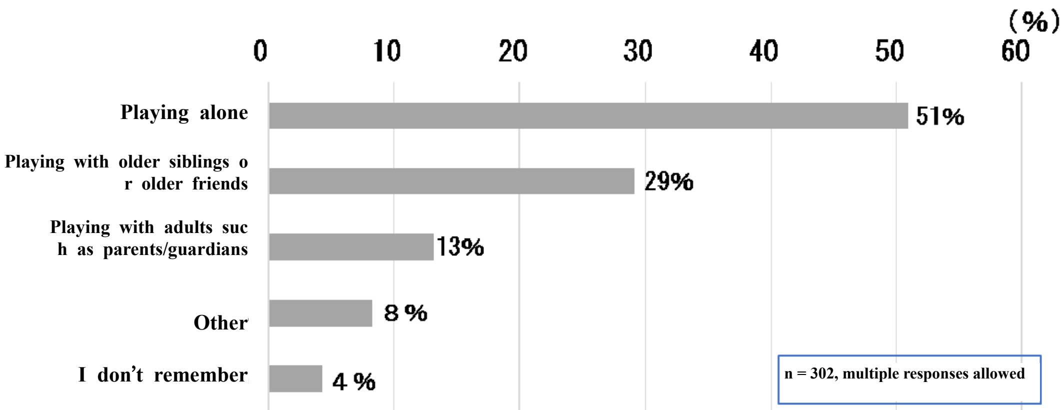


Figure 12. Situation of the child immediately before aspiration

A total of 302 parents/guardians of a child who had the experience of “aspirating” a toy were asked about the owner of the aspirated toy. The responses were as follows (Figure 13):

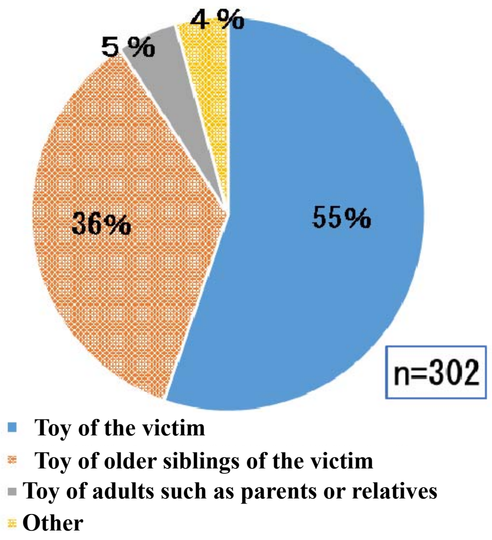


Figure 13. Owner of the aspirated toy

A total of 302 parents/guardians of a child who had the experience of “aspirating” a toy were asked about the appearance/situation of the child at the time of aspiration. The responses were as follows (Figure 14, multiple responses allowed):

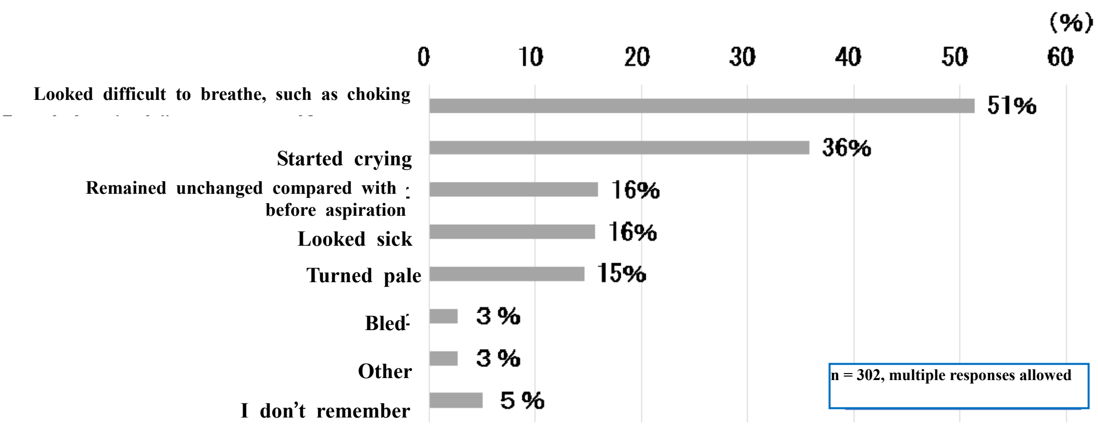


Figure 14. Appearance/situation of the child at the time of aspiration

A total of 302 parents/guardians of a child who had the experience of "aspirating" a toy were asked about the intensity of sickness of the child after aspirating the toy. The results showed that the majority (293 respondents, 97%) responded that their child had no sequelae, with 8 (3%) responding that "their child had a sequela" and 1 (0.3%) responding that "their child died" (Table 4). The questionnaire survey could not collect more information and no interview could be conducted.

Table 4. Cases of responses of "had a sequela" or "died"[46]

Case of accidents	Age (in months)	Type of toys	Shape of toys	Size of toys	Appearance of the child in case of aspiration
Death	I don't remember	Food-shaped	Flat	6~10 mm	Playing alone. The face's color changed. Looked difficult to breathe, such as choking.
Sequela	Under 6 months	Marble	Sphere/cube	6~10 mm	Playing with older siblings. Looked difficult to breathe, choking. Looked sick. Looked sick. Started crying.
Sequela	6 months to 1 year	Block	Flat	21~30 mm	Playing with adults such as parents/guardians. Looked difficult to breathe, such as choking.
Sequela	1 to 1.5 years	Marble	Sphere/cube	11~20 mm	Playing alone. Looked sick.
Sequela	1 to 1.5 years	Toy bullet	Sphere/cube	6~10 mm	Playing with older siblings. Started crying.
Sequela	1 to 1.5 years	Playing house toys	Column/cuboid	11~20 mm	Playing with older siblings. The face's color changed. Looked difficult to breathe, such as choking.
Sequela	1 to 1.5 years	Toy bullet	Sphere/cube	6~10 mm	Playing with older siblings. Looked difficult to breathe, such as choking.
Sequela	2 years	Battery from a toy	Flat	21~30 mm	Playing with siblings or friends of similar ages. Looked difficult to breathe, choking. Looked sick.
Sequela	2 years	Small ball	Sphere/cube	11~20 mm	Playing alone. Looked difficult to breathe, such as choking. Bled.

[46] The statements for each column in Table 4 are the same text in the choices shown in Sections 4.1.2 (2) and (3) and do not reflect detailed situations of individual accidents. Sequelae are also unspecified.

(3) Characteristics of Toys

A total of 302 parents/guardians of a child who had the experience of “aspirating” a toy were asked about the type of the aspirated toy. The results showed that “marbles” were the most common response, followed by “bead-based toys” and “small balls” (Figure 15).

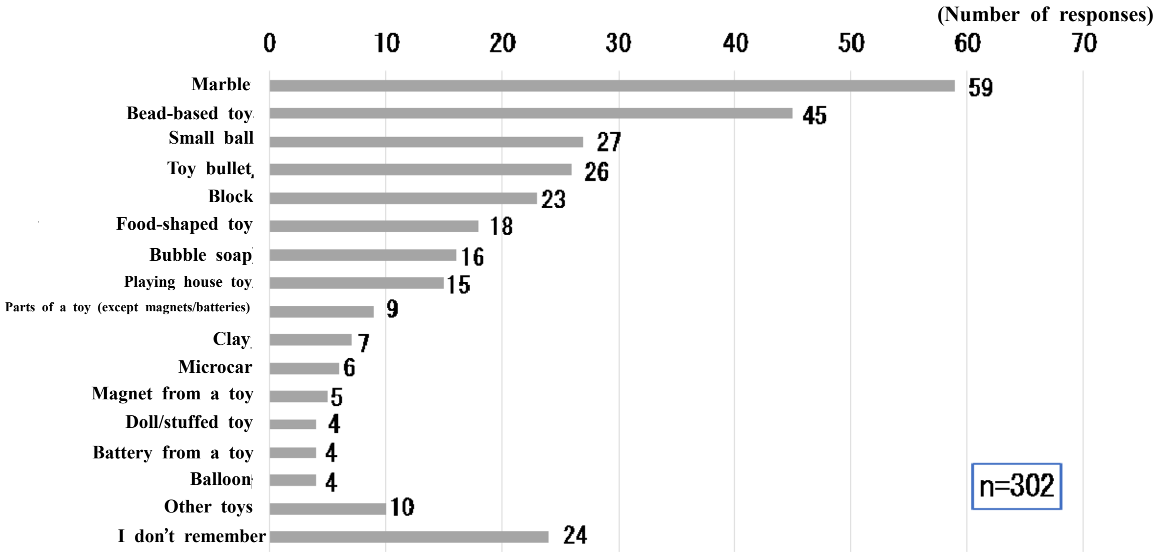


Figure 15. Type of the toy

A total of 302 parents/guardians of a child who had the experience of “aspirating” a toy were asked about the size of the aspirated toy. The results showed that “6 to 10 mm” accounted for 40% of the responses (Figure 16). In addition, an interview on the shape of the toy showed that “objects of the same size when viewed from any plane (such as spheres and cubes)” accounted for 49% of the responses (Figure 17).

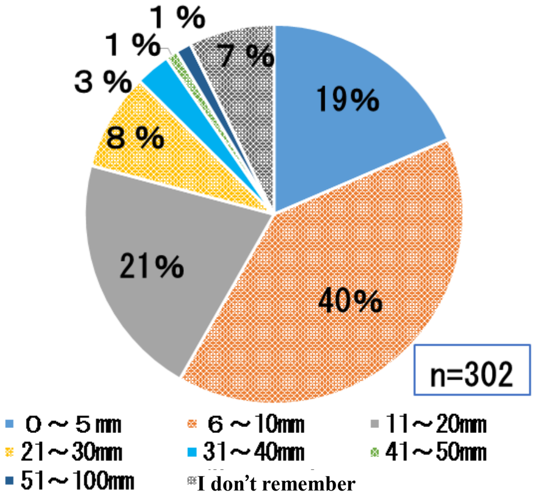


Figure 16. Size of the toy

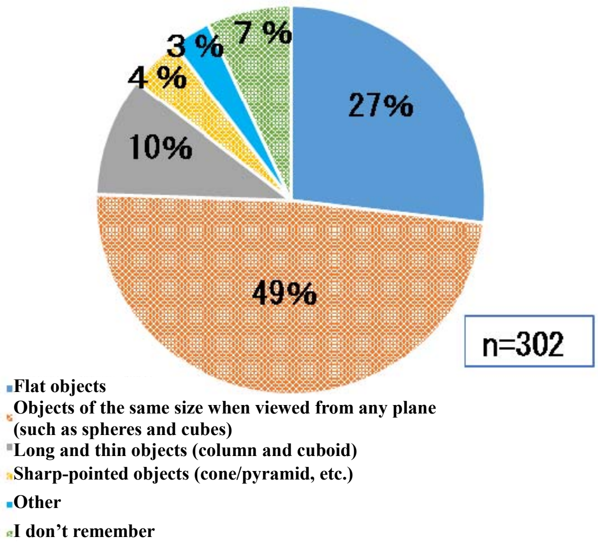
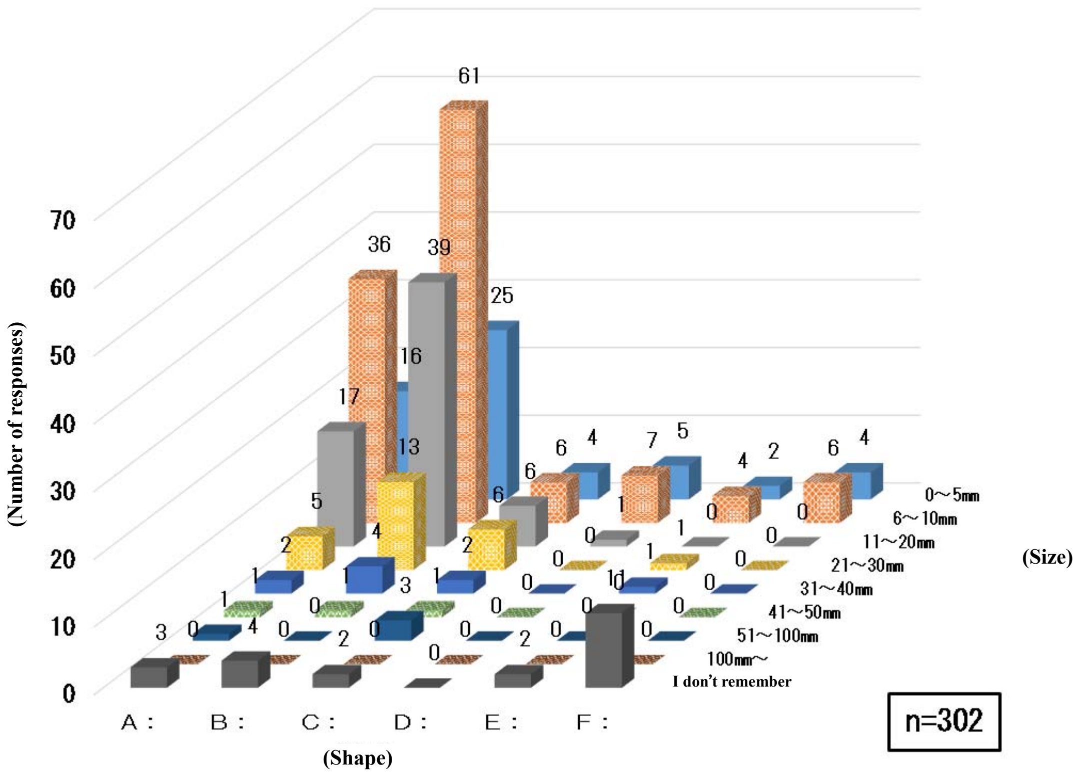


Figure 17. Shape of the toy

In the context of Figure 16 and Figure 17, a question was asked about the relationship between the size and shape of the aspirated toy and the results showed that the combination of “6 to 10 mm” and “objects of the same size when viewed from any plane (such as spheres and cubes)” was the most common (observed in 61 responses). The combination of “11 to 20 mm” and “objects of the same size when viewed from any plane (such as spheres and cubes)” was the next most common response (observed in 39 responses), followed by the combination of “6 to 10 mm” and “flat objects” (observed in 36 responses) (Figure 18).



A : Flat objects
B : Objects of the same size when viewed from any plane (such as spheres and cubes)
C : Long and thin objects (column and cuboid)
D : Sharp-pointed objects (cone/pyramid, etc.)
E : Other
F : I don’t remember

Figure 18. Relationship between the size and shape of the toy

Among the 302 parents/guardians of a child who had the experience of "aspirating" a toy, data from 142 respondents who provided specific responses on the age (in months) of the child at the time of the accident and the size of the toy were used to construct a scatter diagram of the relationship among the age (in months) of children[47], the size of aspirated toys[48], and the intensity of sickness.[49] The results showed that children younger than 3 years were more likely to aspirate toys not larger than approximately 30 mm in size (Figure 19).

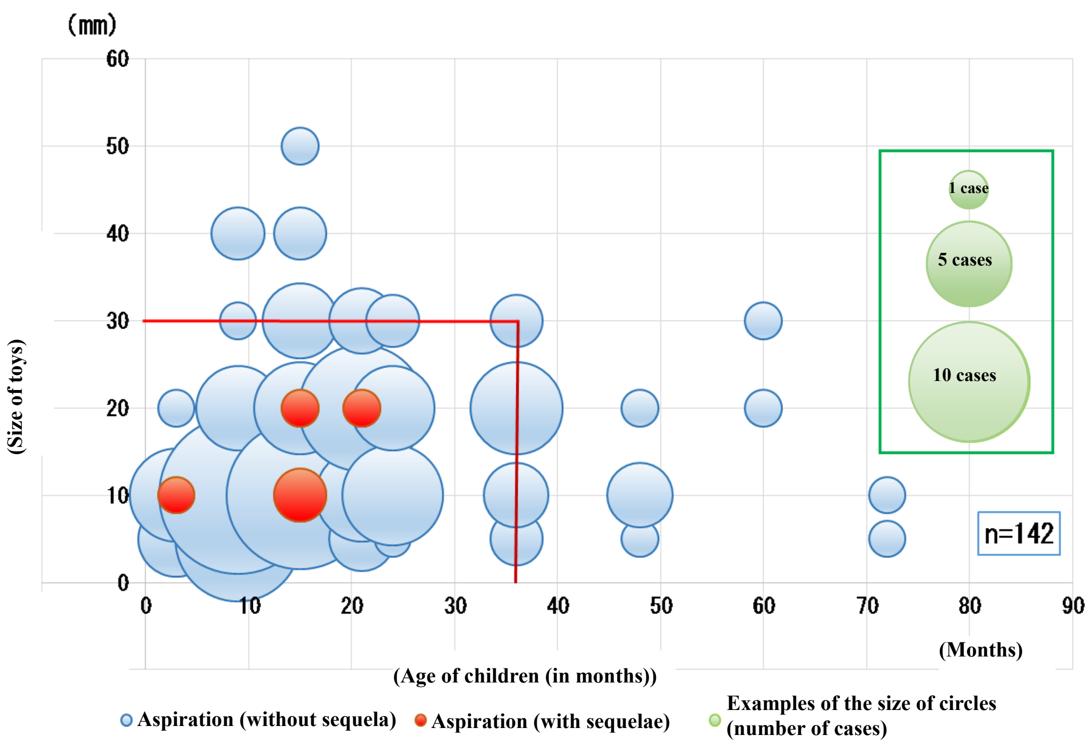


Figure 19. Relationship among age (in months) of the child, size of the toy, and presence/absence of sequelae

A total of 302 parents/guardians of a child who had the experience of "aspirating" a toy were asked about the color of the aspirated toy. The results showed that the most

[47] In the questionnaire survey, the age of children younger than two years was input in 6-month units and therefore the intermediate value was included. For example, the age between one year of age and one year and six months of age was handled as 15 months of age.
[48] In the questionnaire survey, the size of toys was input in 5-mm units and therefore the maximum value was included. For example, a size of 6 to 10 mm was handled as 10 mm.
[49] Among data on 302 cases of aspiration of toys, data on 142 cases in which the shape of toys was limited to the most common response "objects of the same size when viewed from any plane (such as spheres and cubes)" (49%) were used, excluding data in which the size of toys and the age (in months) of children were unspecified.

common colors were blue, white, and red (Figure 20).

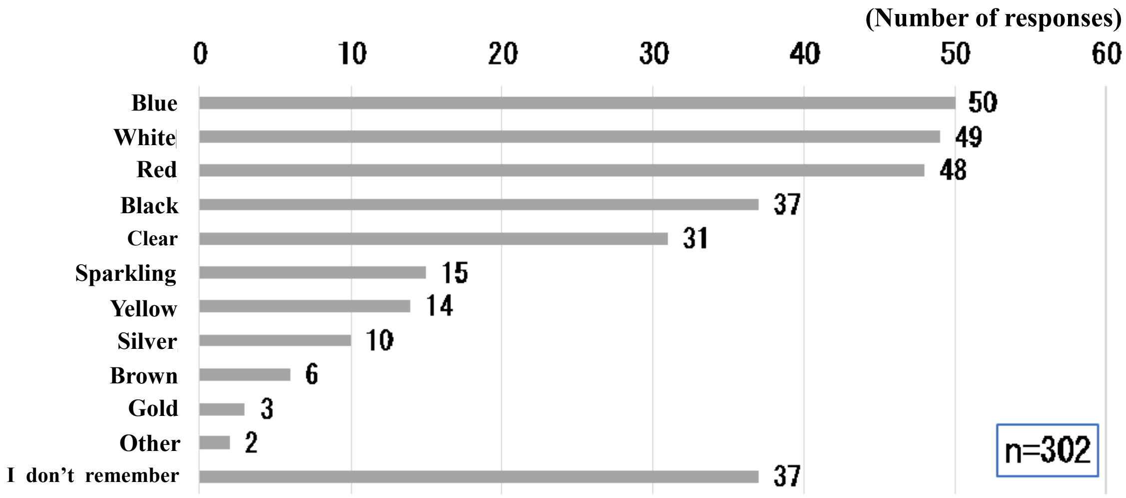


Figure 20. Color of the toy

As with the color, a question was asked about the material of the aspirated toy and the results showed that plastic was the most common (Figure 21).

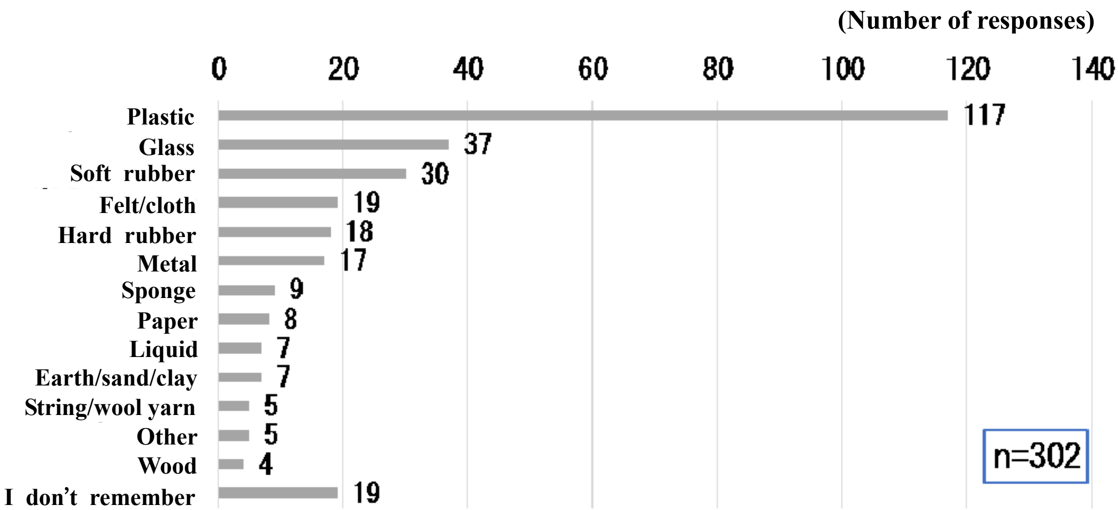


Figure 21. Material of the toy

It should be noted that the above characteristics of "aspirated" toys such as the size, shape, color, and material of toys tended to be similar to the characteristics of "accidentally ingested" toys or "almost accidentally ingested" toys.

(4) Storage of Toys

A total of 947 parents/guardians of a child who had the experience of "aspirating/accidentally ingesting/almost accidentally ingesting" a toy and 350 parents/guardians of a child who "had never aspirated or accidentally ingested" a toy or stationery product were asked about whether the location to store toys was predetermined. The results showed that approximately 80% parents/guardians in both groups responded that the storage location was "predetermined" (Figure 22).

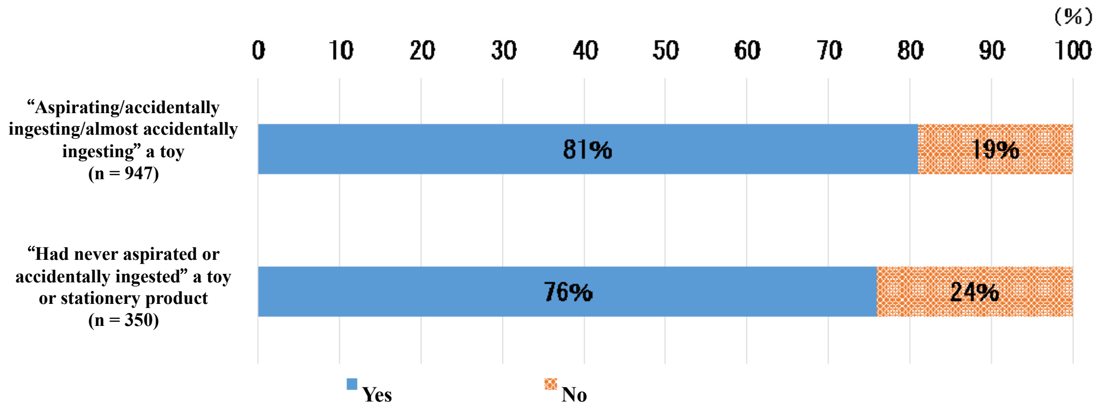


Figure 22. Is the location to store toys predetermined?

The parents/guardians who responded that the location to store toys was "predetermined," as shown in Figure 22, were asked about the frequency of pulling toys together. The results showed that "pulling toys together after each play session" was the most common response, which was provided by 55% of respondents in the group of parents/guardians of a child who "had never aspirated or accidentally ingested" a toy or stationery product (Figure 23).

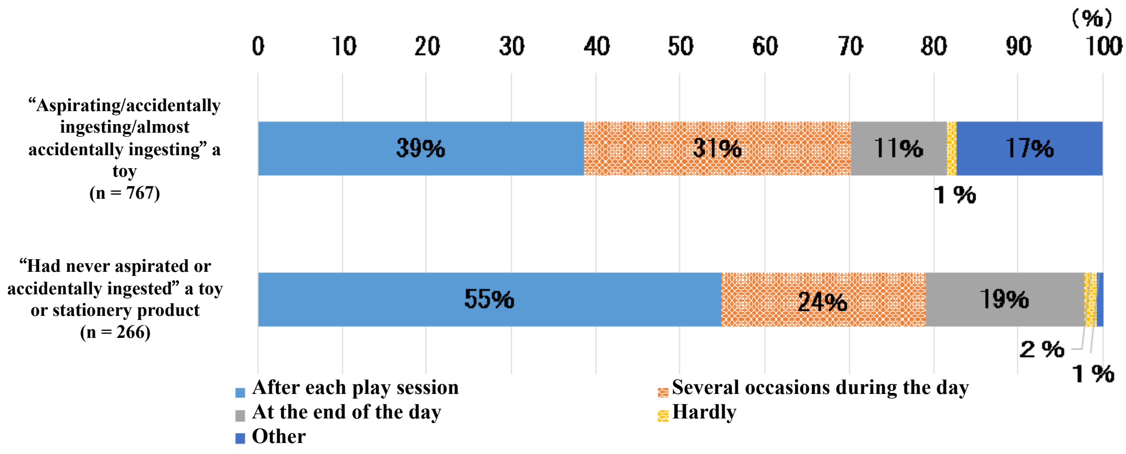


Figure 23. Frequency of pulling toys together

The parents/guardians who responded that the location to store toys was “predetermined,” as shown in Figure 22, and who had two or more children were asked about whether siblings played with one another’s toys when they were together. The results showed that 584 of 653 (89%) parents/guardians of a child who had the experience of “aspirating/accidentally ingesting/almost accidentally ingesting” a toy and 153 of 200 (77%) parents/guardians of a child who “had never aspirated or accidentally ingested” a toy or stationery product responded that “siblings played together.” Siblings were found to be slightly less likely to play with one another’s toys in the households without than with the experience of “aspiration/accidental ingestion” in children (Figure 24).

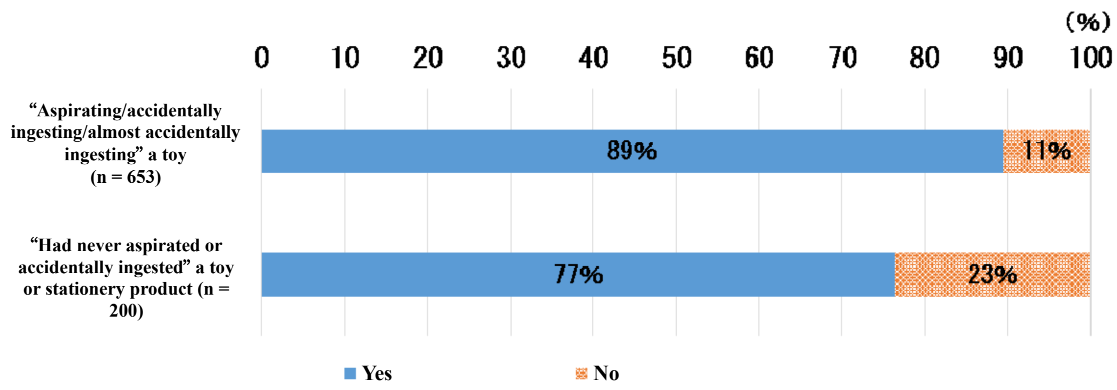


Figure 24. Do siblings play with one another’s toy?

The parents/guardians who responded “siblings played together,” as shown in Figure 24, were asked about whether toys of older siblings were stored out of the reach of younger siblings. The results showed that 374 of 584 (64%) parents/guardians of a child who had the experience “aspirating/accidentally ingesting/almost accidentally ingesting” a toy and 105 of 153 (69%) parents/guardians of a child who “had never aspirated or accidentally ingested” a toy or stationery product responded “No” (Figure 25).

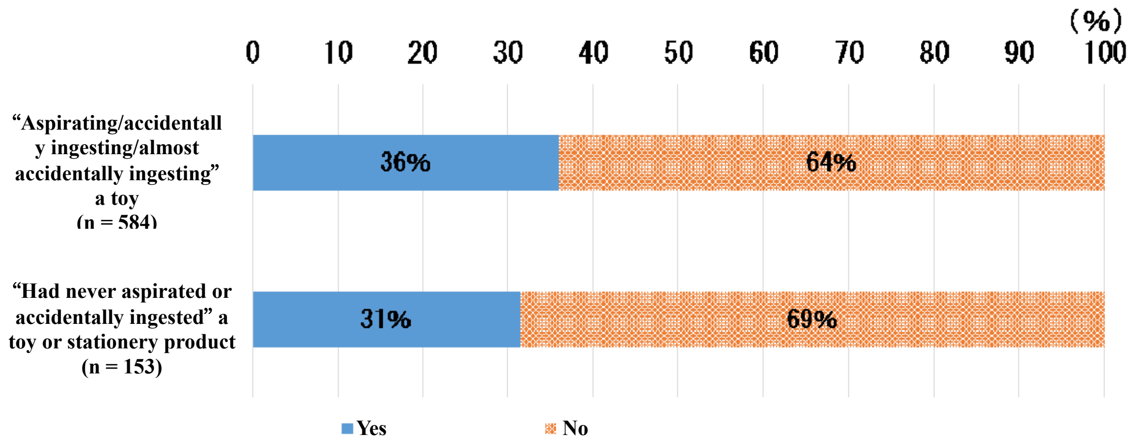


Figure 25. Are toys of older siblings stored out of the reach of younger siblings?

The parents/guardians who responded “No,” as shown in Figure 25, were asked about the reason. The results showed that 289 of 374 (77%) parents/guardians of a child who had the experience of “aspirating/accidentally ingesting/almost accidentally ingesting” a toy and 75 of 105 (71%) parents/guardians of a child who “had never aspirated or accidentally ingested” a toy or stationery product responded that “siblings played with the same toys” (Figure 26, multiple responses allowed).

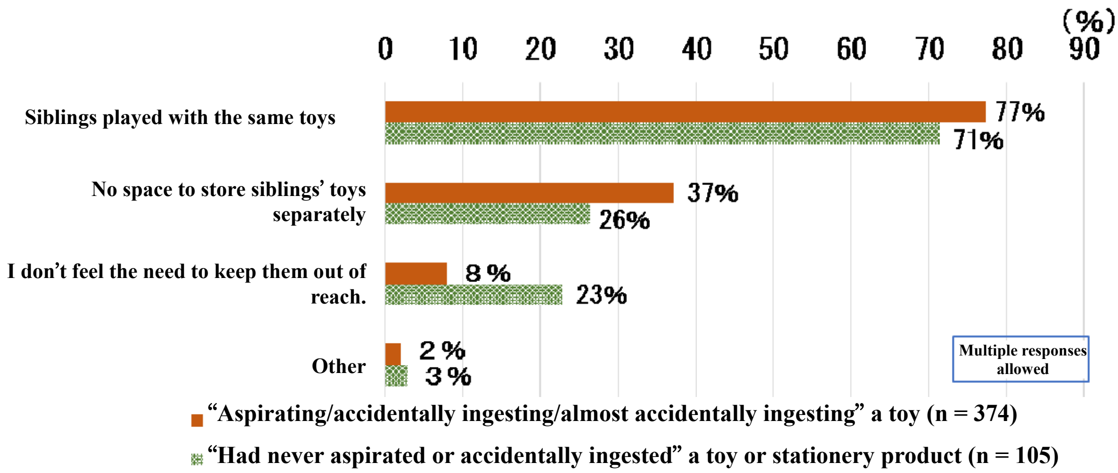


Figure 26. Reason why toys of older siblings are not stored out of the reach of younger siblings

(5) Purchase of Toys

A total of 947 parents/guardians of a child who had the experience of "aspirating/accidentally ingesting/almost accidentally ingesting" a toy were asked about the source of the relevant toy. The results showed that "toy shops (including department stores)" was the most common response that was provided by 307 respondents (Figure 27).

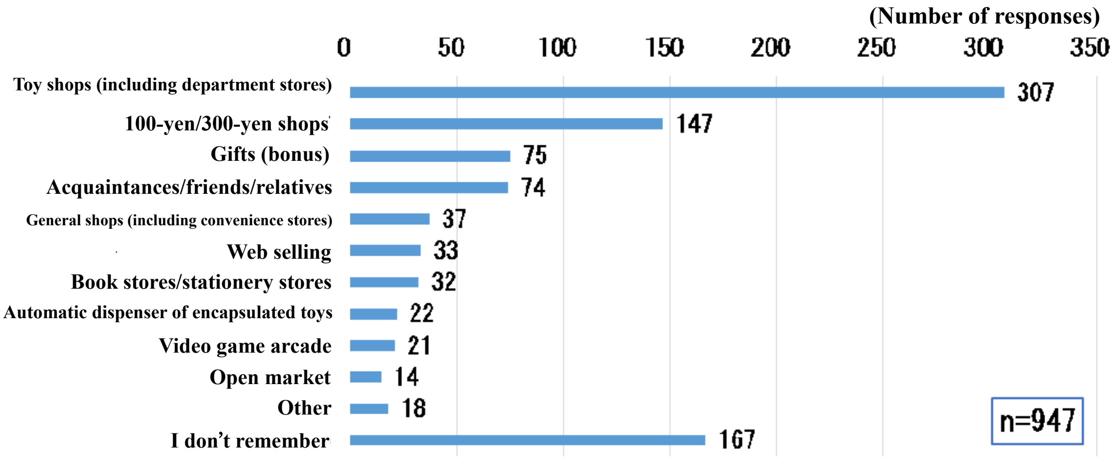


Figure 27. Source of the toy

A total of 947 respondents shown above were analyzed for the source of the toy by age category. The results showed that "toy shops (including department stores)" was more common in the age categories of ≥51 years and "100-yen/300-yen shops" was more common in the age categories of 21 to 40 years (Table 5).

Table 5. Source of the toy by age category (Unit: %)

	Toy shops	100-yen/300-yen shops	Gifts	Acquaintances/friends/relati	General shops	Web selling	Book stores/stationery stores	Automatic dispenser of encapsulated toys	Video game arcade	Open market	Other	I don't remember
Total (n = 947)	32	16	8	8	4	4	3	2	2	2	2	18
21 to 30 years of age (n = 108)	27	19	7	9	9	3	3	6	6	1	2	10
31 to 40 years of age (n = 441)	28	19	10	8	3	6	4	3	2	2	2	15
41 to 50 years of age (n = 168)	36	17	7	9	4	2	4	1	1	1	2	17
51 to 60 years of age (n = 97)	40	6	8	6	3	0	2	2	1	3	2	26
61 to 70 years of age (n = 113)	43	5	5	4	4	0	4	1	4	1	0	28
71 years of age or older (n = 20)	40	15	5	5	15	0	0	0	0	0	5	15

A total of 947 parents/guardians of a child who had the experience of "aspirating/accidentally ingesting/almost accidentally ingesting" a toy and 350 parents/guardians of a child who "had never aspirated or accidentally ingested" a toy or stationery product were asked about what they placed importance on when buying toys. The results showed that the most common responses included "interest of children" and "safety" (Figure 28, multiple responses allowed).

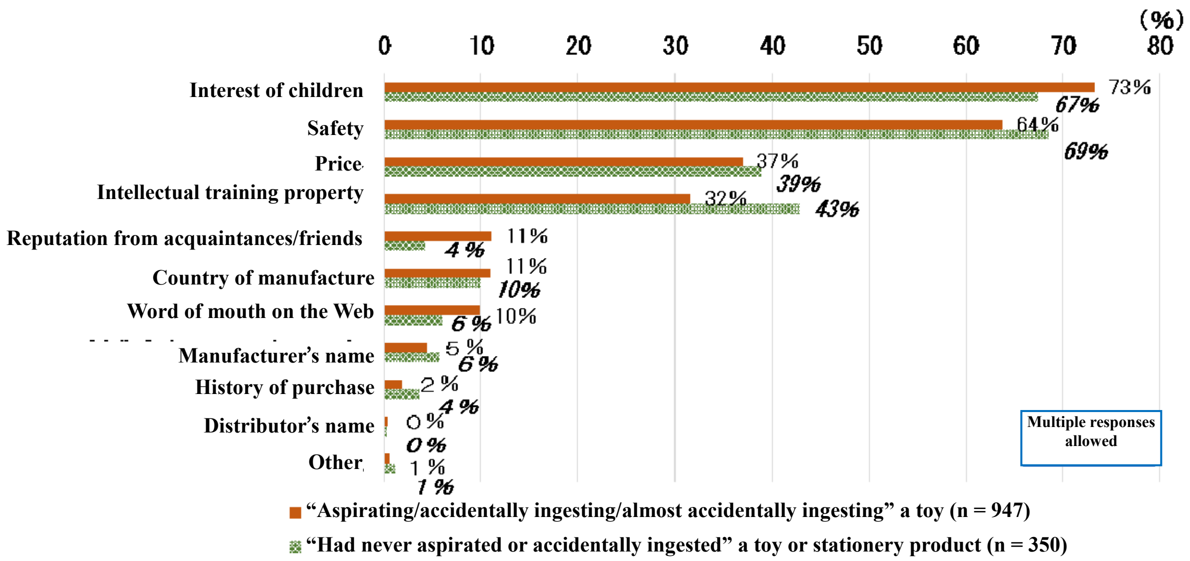


Figure 28. What importance is placed on in buying toys

A total of 947 respondents shown above were analyzed by age category with regard to what they placed importance on when buying toys (Table 6).

"Interest of children," the most common response, tended to be emphasized in all age groups. “Safety” was more likely to be emphasized by respondents aged 51 years or older than respondents aged 50 years or younger. “Prices” was more likely to be emphasized by respondents aged between 21 and 50 years than respondents aged 51 years or older.

Table 6. What importance is placed on when buying toys by age category (Unit: %)

	Interest of children	Safety	Price	Intellectual training property	Country of manufacture	Reputation from acquaintances/ friends	Word of mouth on the Web	Manufacturer's name	History of purchase	Distributor's name	Other
Total (n = 947)	73	64	37	32	32	11	10	5	2	0	1
21 to 30 years of age (n = 108)	69	51	44	26	7	22	14	5	1	2	-
31 to 40 years of age (n = 441)	76	61	41	35	10	10	13	4	2	0	1
41 to 50 years of age (n = 168)	73	61	41	31	12	8	11	1	3	-	1
51 to 60 years of age (n = 97)	66	77	23	29	19	6	4	10	2	1	2
61 to 70 years of age (n = 113)	71	75	27	26	13	13	2	8	1	-	-
71 years of age or older (n = 20)	85	95	15	50	10	10	-	5	-	-	-

The parents/guardians who responded that they placed importance on “safety” when buying toys, as shown in Figure 28, were asked about the basis for determining the safety of toys. The results showed that the more common responses included “size of toys” and “shape of toys” (Figure 29, multiple responses allowed).

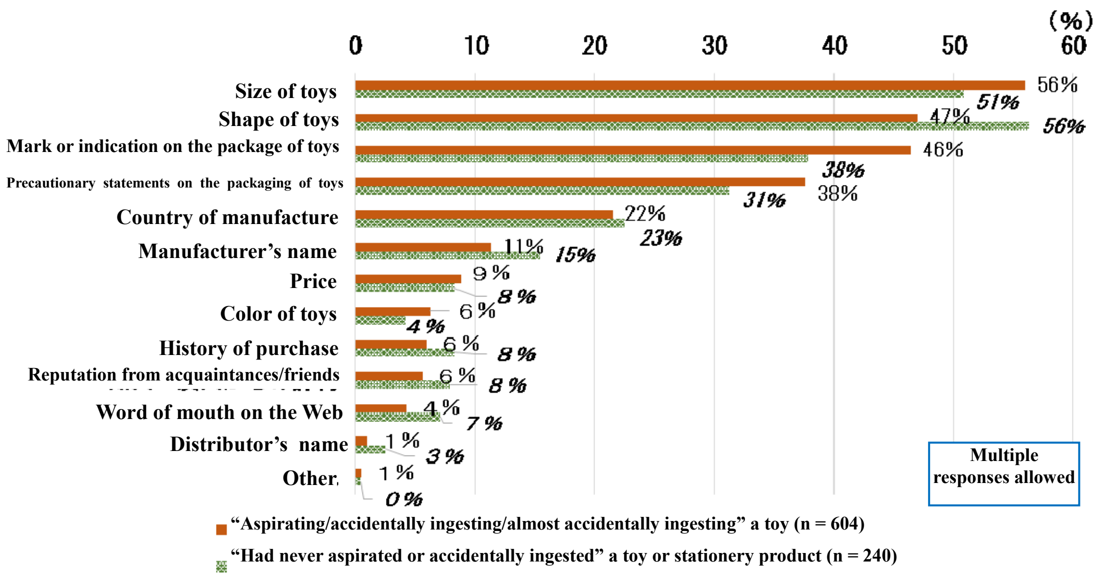


Figure 29. Basis for determining the safety of toys

A total of 947 parents/guardians of a child who had the experience of "aspirating/accidentally ingesting/almost accidentally ingesting" a toy and 350 parents/guardians of a child who "had never aspirated or accidentally ingested" a toy or stationery product were asked about the awareness of the ST Mark (see Figure 3). The results showed that >70% of parents/guardians in both groups responded that they "have seen the mark,"[50] but only <30% of parents/guardians in both groups responded that they "have seen the mark and know its meaning" (Figure 30).

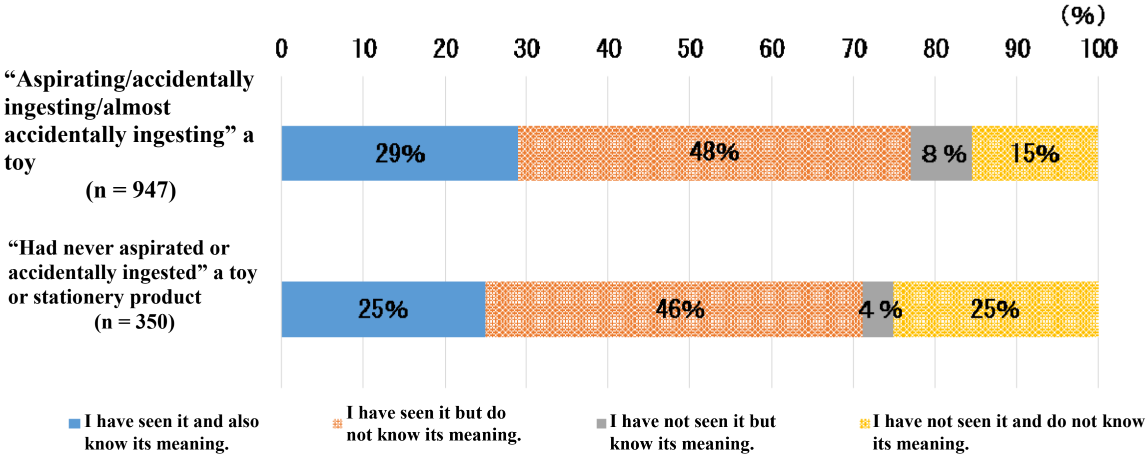


Figure 30. Awareness of ST Mark

The parents/guardians who responded that they "have seen the ST Mark and know its meaning" were asked about whether the presence or absence of the ST Mark contributed to their decision about whether to buy toys. The results showed that approximately 75% of parents/guardians in both groups responded "yes" or "maybe yes" (Figure 31).

[50] The sum of the number of individuals responding "Have seen the ST Mark and also know its meaning" and the number of individuals responding "Have seen the ST Mark but have no idea of its meaning."

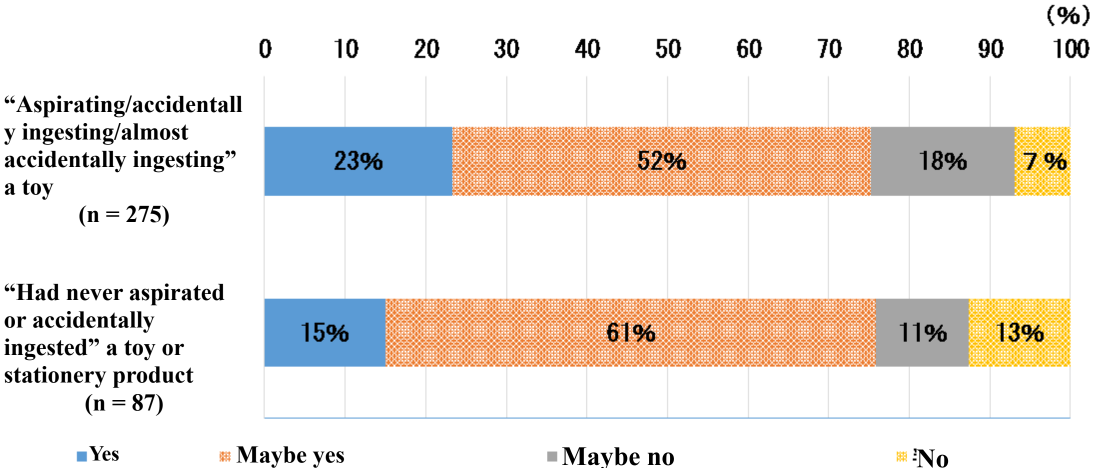


Figure 31. Does the presence or absence of the ST Mark contribute to a decision about whether to buy toys?

The parents/guardians who responded "yes" or "maybe yes" to the question about whether the presence or absence of the ST Mark contributed to their decision on whether to buy toys, as shown in Figure 31, were asked about the reason. The responses were as follows (open-ended description):

• The presence of the ST Mark makes me feel that attention is paid to safety.
• I check toys that appear to be obviously dangerous for the presence of the ST Mark.
• The ST Mark is evidence that safety is confirmed by public institutions and provides reassurance.

A total of 947 parents/guardians of a child who had the experience of "aspirating/accidentally ingesting/almost accidentally ingesting" a toy and 350 parents/guardians of a child who "had never aspirated or accidentally ingested" a toy or stationery product were asked about whether they reviewed instruction manuals when buying toys. The results showed that "reading over the manual" was the most common response, followed by "sometimes reading the manual and sometimes not" (Figure 32).

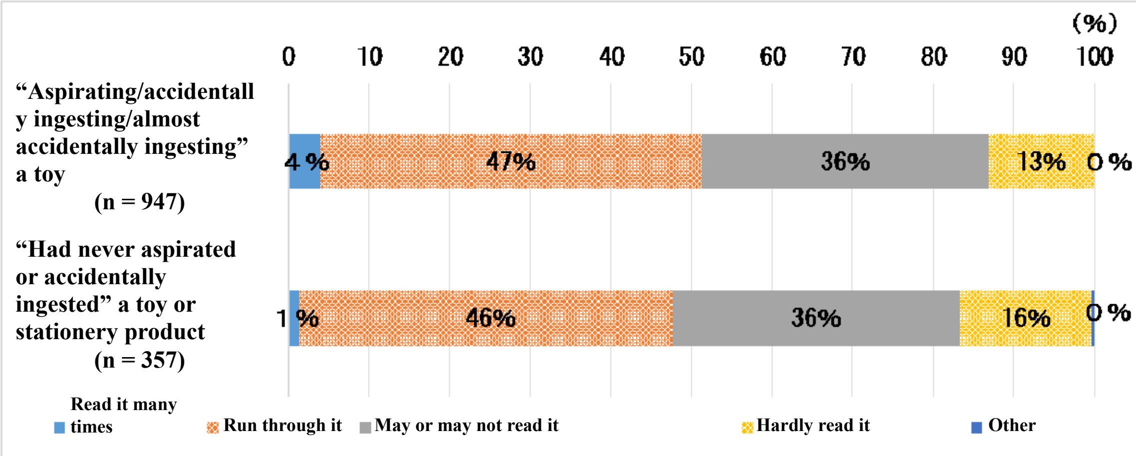


Figure 32. Review of instruction manuals

(6) Verification of Intended Ages for Toys

A total of 947 parents/guardians of a child who had the experience of “aspirating/accidentally ingesting/almost accidentally ingesting” a toy and 350 parents/guardians of a child who “had never aspirated or accidentally ingested” a toy or stationery product were asked about whether they verified the intended age for toys when buying them. The results showed that the combined percentage of parents/guardians who responded “yes” and “maybe yes” was 83% for the parents/guardians of a child who had the experience of “aspirating/accidentally ingesting/almost accidentally ingesting” a toy and 77% for the parents/guardians of a child who “had never aspirated or accidentally ingested” a toy or stationery product, indicating that approximately 80% of parents/guardians in both groups verified the intended age for toys when buying them (Figure 33).

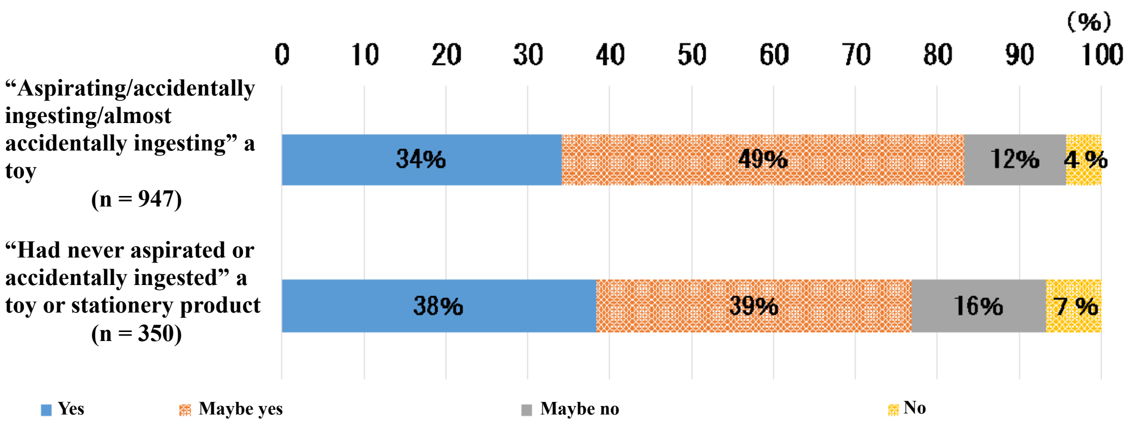


Figure 33. Do you verify the intended age for toys when buying them?

The parents/guardians who responded “yes” and “maybe yes,” as shown in Figure 33, were asked about whether they bought toys even if there were no children of the intended ages for them in the household. The results showed that the combined percentage of parents/guardians who responded “yes” and “maybe yes” was 79% (619/789) for the group of parents/guardians of a child who had the experience of “aspirating/accidentally ingesting/almost accidentally ingesting” a toy and 65% (175/269) for the group of parents/guardians of a child who “had never aspirated or accidentally ingested” a toy or stationery product (Figure 34).

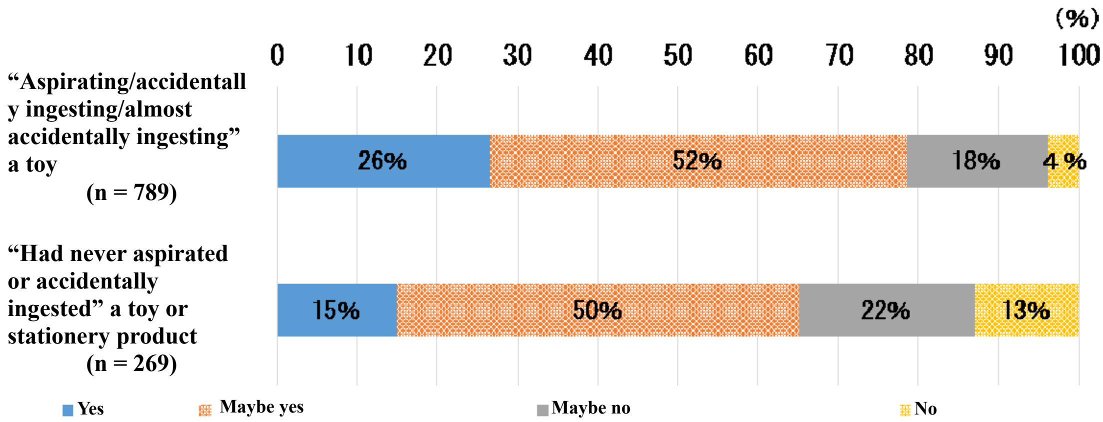


Figure 34. Do you buy toys even if there are no children of the intended age for them in the household?

In the context of Figure 34, the parents/guardians who responded “yes” or “maybe yes” to the question about whether they bought toys even if there were no children of the intended ages for them in the household were asked about the reason. The responses were as follows (open-ended description):

- Intended ages are only as a guide and the fact remains that a toy can be dangerous at any age if a child makes a mistake in using the toy, even though the child reaches the intended age for the toy. Conversely, I think that a child can use a toy safely if the development of the child is appropriate for the toy, even though the child does not reach the intended age for the toy.
- Although I avoid buying a toy that a younger sibling obviously seems likely to swallow, I sometimes consider the feelings of an older sibling and buy a toy that the older sibling likes.
- Although I buy a toy considering safety, I want to set a high hurdle for my child to

raise the level of the child by giving the child a toy that is intended for children slightly older than the age of the child in months.

- Since many toys are intended for children aged three years and older and my child is sometimes not interested in toys intended for children under three years when the child is younger than three years, I bought toys intended for children aged three years and older. However, I bought only toys bearing the Mark.

(7) Intended Ages and Sizes of Toys

A total of 947 parents/guardians of a child who had the experience of "aspirating/accidentally ingesting/almost accidentally ingesting" a toy were asked about the intended age indicated on the toy. The results showed that the majority of respondents (53%) did "not remember" it. For the respondents who remembered it, "≥3 years but <6 years" was the most common intended age for toys, followed by "≥18 months but <3 years" (Figure 35).

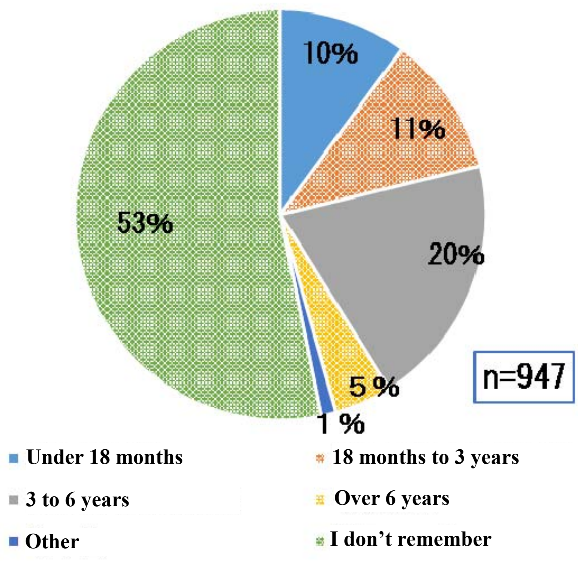


Figure 35. Intended age indicated on the toy

Among the 947 parents/guardians of a child who had the experience of "aspirating/accidentally ingesting/almost accidentally ingesting" a toy, data on 443 parents/guardians who provided specific responses on the intended age were used to show the relationship between the intended age for the toy and the size of the toy in Figure 36.

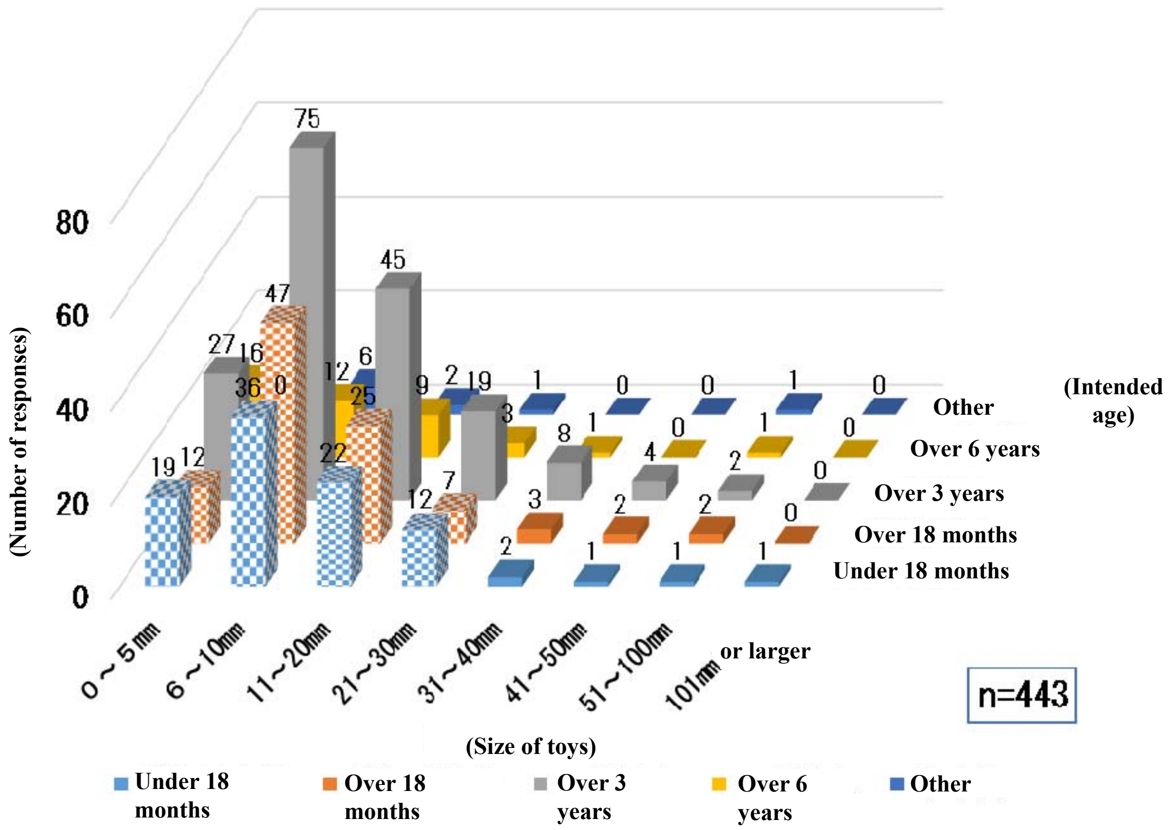


Figure 36. Relationship between the intended age indicated on the toy and the size of the toy

As described in Section 3.3.3 (1), the ST Standard requires that toys intended for children under 36 months, removable components thereof, etc. shall not fit entirely, whatever their orientation, into the predetermined small parts cylinder.
However, it is possible that toys constituting the shaded areas in Figure 36 are of sizes that fit into the small parts cylinder while intended for children under 36 months. Although it is unknown whether the relevant toys were given the ST Mark, it is somewhat likely that ineligible toys for safety standards, including the ST Standard, or international standards cause aspiration or ingestion accidents.

(8) Situations and Responses of Parents/Guardians at the Time of Occurrence of Accidents

A total of 947 parents/guardians of a child who had the experience of "aspirating/accidentally ingesting/almost accidentally ingesting" a toy were asked about the situation at the time of occurrence of accidents. The results showed that "a little away from the child" was the most common response which was provided by 460 parents/guardians (49%), followed by "very close to the child," provided by 424 parents/guardians (45%), indicating that accidents occurred even when parents/guardians were very close to their children (Figure 37).

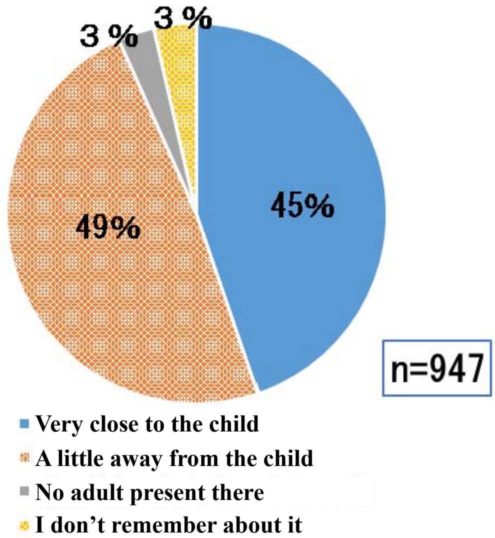


Figure 37. Situations of parents/guardians at the time of "aspiration/accidental ingestion/almost accidental ingestion"

A total of 607 parents/guardians of a child who had the experience of "aspirating/accidentally ingesting" a toy were asked about the response made by them. The results showed that "putting their fingers in the child's mouth" was the most common response which was provided by 310 parents/guardians (51%), followed by "patting the child's back," provided by 232 parents/guardians (38%), and "turning the child upside down," provided by 93 parents/guardians (15%). On the other hand, only 26 (4%) and 22 (4%) respondents practiced "back blows" and the "Heimlich maneuver," respectively, which were recommended actions for accidents included in the maternal and child health handbook, etc. (Figure 38, multiple responses allowed).

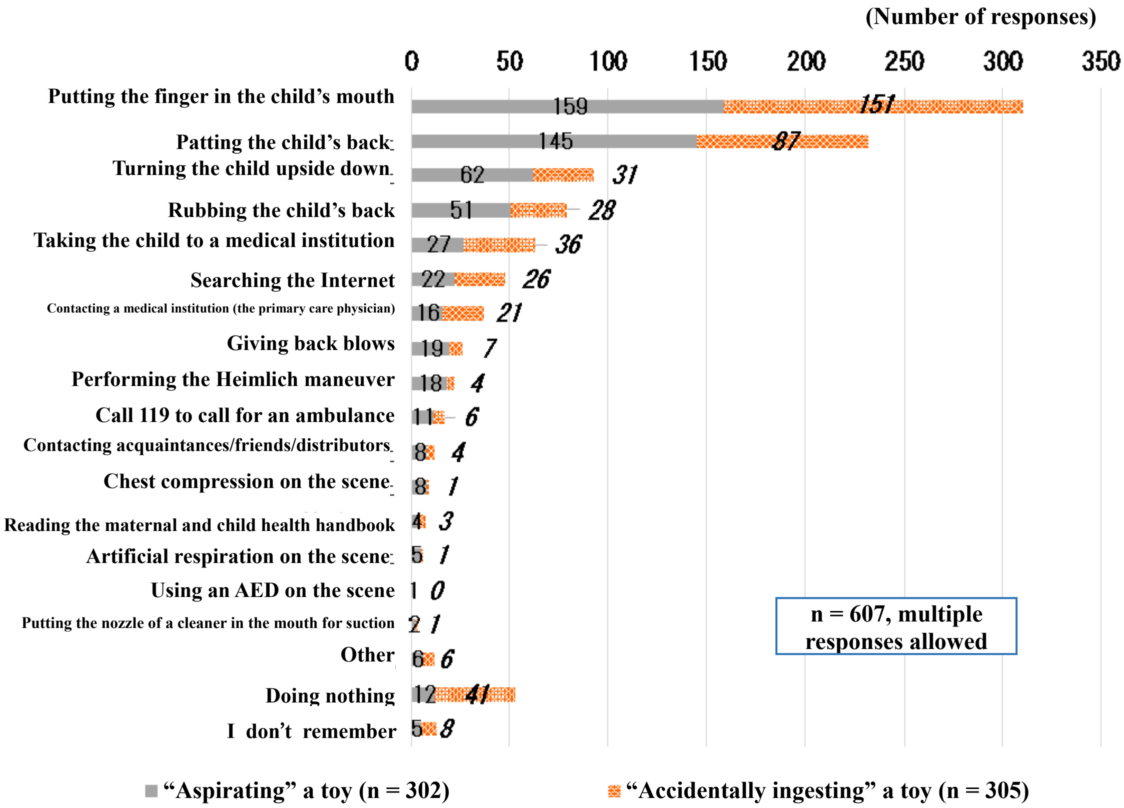


Figure 38. Responses made by parents/guardians at the time of "aspiration/accidental ingestion"

(9) Awareness of Parents/Guardians about Responses to Accidents

All the respondents to the questionnaire (2,164 respondents) were asked about the actions they could come up with in case of aspiration or accidental ingestion in the child. The results showed that "patting the child's back" was the most common response, provided by 71% of respondents, followed by "putting the finger in the child's mouth" (59%) and "turning the child upside down" (39%). The percentage of individuals responding that they could come up with the "back blow maneuver" and "Heimlich maneuver," which were recommended actions in case of accidents included in the maternal and child health handbook, etc., were again 24% and 19%, respectively, both lower than those for the top three actions (Figure 39, multiple responses allowed).

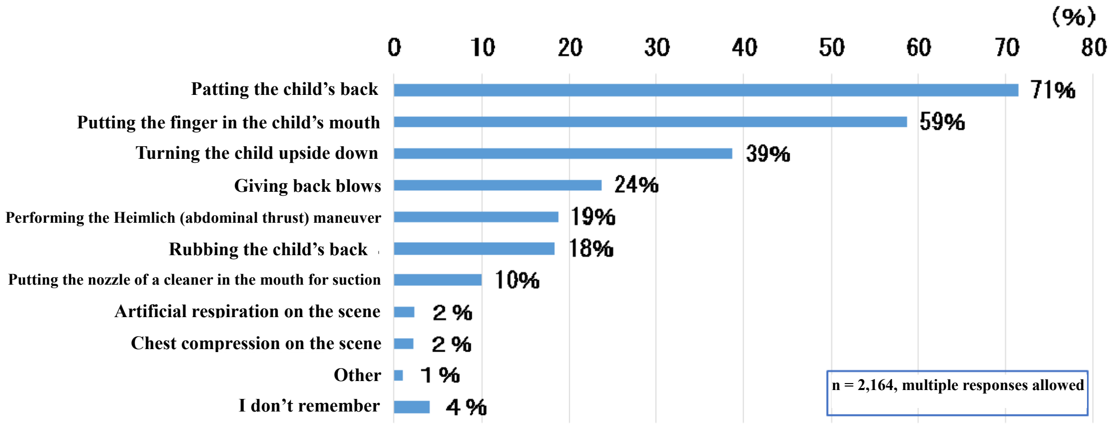


Figure 39. What actions do you come up with in case of aspiration or accidental ingestion in your child?

The parents/guardians responding that they came up with performing the "back blow maneuver" (n = 519) or "Heimlich maneuver" (n = 404), as shown in Figure 39, were asked about their practical level. The results showed that the largest percentage of parents/guardians responded "I can perform the maneuver but cannot instruct others about it" for either maneuver. On the other hand, the smallest percentage of parents/guardians responded "I do not know the procedure in detail and cannot perform it" (<10%). It is probable that those who can come up with the "back blow maneuver" or "Heimlich maneuver" have a certain level of knowledge about the maneuver and can perform it (Figure 40).

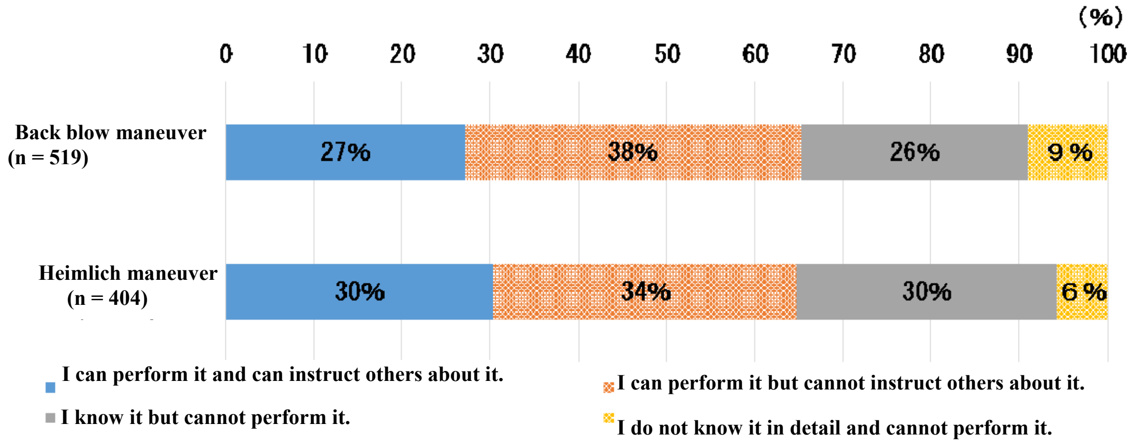


Figure 40. Practical level of the "back blow maneuver" and "Heimlich maneuver"

Among 2,164 respondents to the questionnaire, a total of 2,078 respondents responding that they knew actions to be taken were asked about the route through which they had learned about actions to be taken. The results showed that "TV/magazines" was the most common (18%), followed by "information contained in the maternal and child health handbook" (17%) and "the Internet" (14%) (Figure 41, multiple responses allowed).

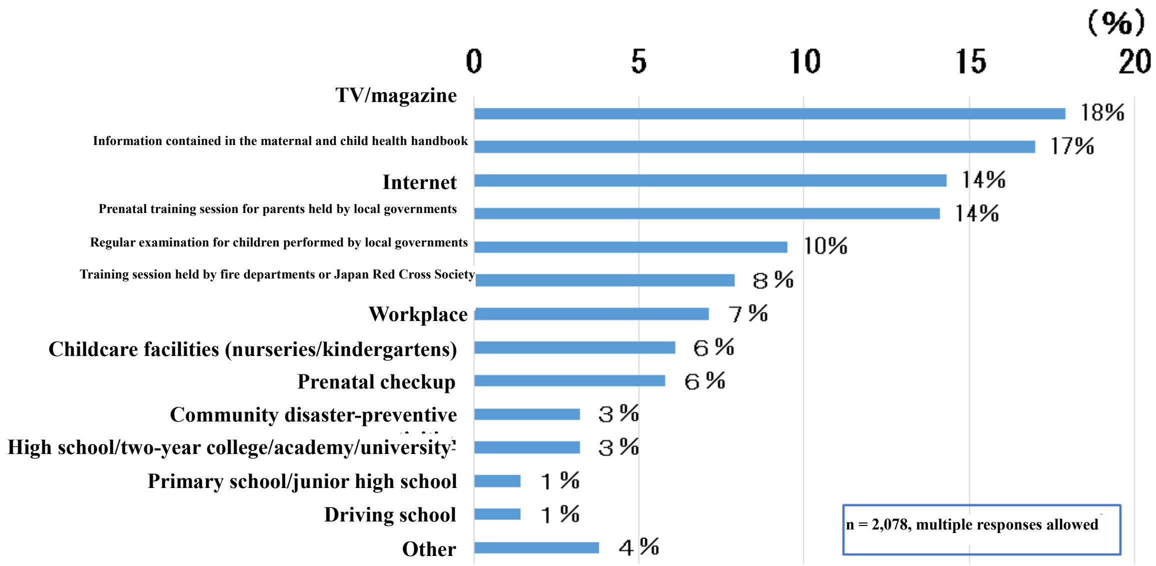


Figure 41. Route through which actions to be taken were learned

Similarly, a total of 2,078 respondents responding that they knew actions to be taken were asked about the experience of receiving training of actions to be taken. The results showed that "None" accounted for the largest portion (65%), followed by "Just one occasion" (19%) and "About two to four occasions" (14%) (Figure 42).

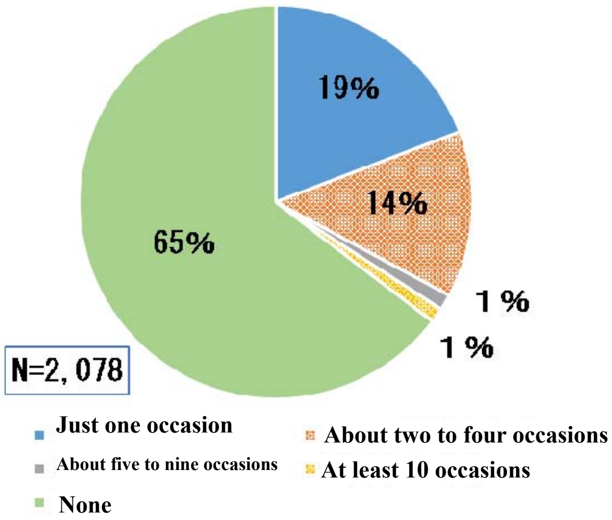


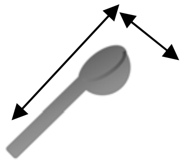
Figure 42. Experience of receiving training of actions to be taken

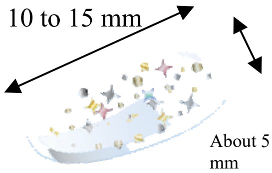
4.1.3 Interview and its Results

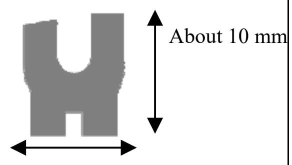
Among the respondents to the questionnaire survey, selected parents/guardians who responded that their child had the experience of aspirating a toy were interviewed on the detailed situation at the time of aspiration by visit to their home or by phone. A list of the interview results and an overview of each case are shown below (Table 7).

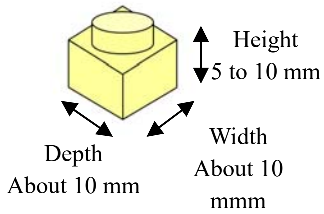
Table 7. List of the Results of Hearing Investigation

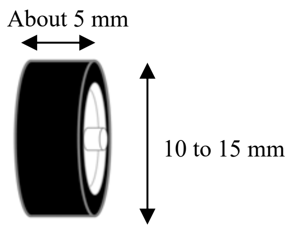
	Age (in months)	Type of toy	Shape of toy	Size of toy	Appearance of the child in case of aspiration
1	1 year and 2 months	Accessory of a doll	Spoon	Length: About 10 mm Width: About 2 mm	The child had slightly tearful eyes and was retching
2	1 year and 3 months	Part of a toy	Disc	Diameter: About 10 mm Thickness: About 10 mm	The child's complexion stayed unchanged, the victim seemed to be choking on something.
3	1 year and 6 months	Part of a plastic model	Tube with a U-shaped groove	Diameter: About 10 mm Height: About 10 mm	The child heartily complained of something, crying and pointing to the child's throat with the child's finger
4	1 year and 7 months	Block toy	Block	Depth: About 10 mm Width: About 10 mm Height: 5 to 10 mm	The child was choking distressfully and giving an unusual cough
5	1 year and 10 months	Part of a toy	Disc	Diameter: 10 to 15 mm Thickness: About 5 mm	The child appeared to have gotten slightly teary, but did not choke.
6	2 years	Part of a doll	Curved cuboid	Length: 5 to 10 mm Width: About 3 mm	The child was distressfully holding her neck
7	2 years and 3 months	Part of a toy	Sphere	Diameter: About 10 mm	The child blushed in the face and was giving slightly choking coughs.

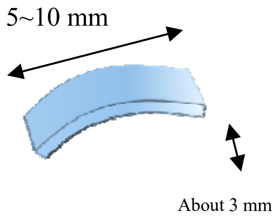
Case 1	Case of aspiration of an accessory of a doll	Aspirated object (Image)
Age (in months) of the victim	One year and two months	
Persons at the scene	Father, mother, older brother (age of four years), younger brother (victim)	
Time of occurrence	After dinner, November 2016	
Overview		
When the older brother was playing house with dolls in the living room, the victim was playing with him, going around him. Dolls and their accessories were scattered in the room. The father was in another room and could not see how his children were doing, whereas the mother was washing dishes in the kitchen, turning her back to her children. When the father went to the living room, the victim was sobbing. Because the victim had slightly tearful eyes and was retching, the father instantly thought that the victim had ingested something and put his fingers into the victim's mouth. When the father put his fingers into the back of the throat, the victim belched out an accessory of a doll (a spoon-like object). The victim had no sequela.		

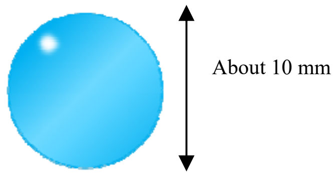
Case 2	Case of aspiration of a part of a toy (a marble-like object)	Aspirated object (Image)
Age (in months) of the victim	One year and three months	
Persons at the scene	One parent, child (victim)	
Time of occurrence	Around 17:00, September 2016	
Overview		
While the parent was preparing dinner in the kitchen (approximately three meters away from the child), the victim was playing alone, seated beside a toy box in front of the TV. When the parent happened to bring tea to the victim, the parent noticed that the victim looked different from usual. Although the victim's complexion stayed unchanged, the victim seemed to be choking on something. After a while, the parent patted the victim's back and a clear plastic part of a toy with glitter, like a marble, with a diameter of 10 to 15 mm, came out of the victim's mouth. The victim had no sequela.		

<table>
<tr><td>Case 3</td><td>Case of aspiration of a part of a plastic model</td><td>Aspirated object (Image)</td></tr>
<tr><td>Age (in months) of the victim</td><td>One year and six months</td><td rowspan="4">Cross section from the side
</td></tr>
<tr><td>Persons at the scene</td><td>Grandparents, uncle (age of 14 years), uncle’s friend (age of 14 years), uncle (age of 8 years), grandchild (victim)</td></tr>
<tr><td>Time of occurrence</td><td>Around evening, February 2017</td></tr>
<tr><td colspan="2">Overview</td></tr>
<tr><td colspan="3">The two uncles and the uncle’s friend were playing, building a plastic model, in the living room, where the victim was also present. When preparing for dinner in the kitchen (next to the living room), the grandmother heard the uncles and the friend making scenes. When the grandmother went to see what they were doing, the uncles and the friend were looking for a part of the plastic model and the grandmother also looked for it but could not find it.
Then, because the victim heartily complained of something, crying and pointing to the victim’s throat with the victim’s finger, the grandmother took the victim to a familiar hospital. Medical examination revealed that a tubular plastic model part with a U-shaped groove was lodged in the throat. The physician inserted a camera through the victim’s nose and took out the plastic model part. Over subsequent several days, the victim appeared to be afraid of ingesting food, but had no sequela.</td></tr>
</table>

<table>
<tr><td>Case 4</td><td>Case of aspiration of a block toy</td><td>Aspirated object (Image)</td></tr>
<tr><td>Age (in months) of the victim</td><td>One year and seven months</td><td rowspan="4">
</td></tr>
<tr><td>Persons at the scene</td><td>One parent, older brother (age of five years), younger sister (victim)</td></tr>
<tr><td>Time of occurrence</td><td>Around 19:00, October 2016</td></tr>
<tr><td colspan="2">Overview</td></tr>
<tr><td colspan="3">When the parent was preparing for dinner, the older brother came to the parent to say “She has ingested a toy.” The parent rushed to the victim and found the victim choking distressfully and giving an unusual cough. The parent opened the victim’s mouth wide and looked into it, but found nothing. The parent thought that any toy that might be stuck in a point out of sight should be completely ingested and gave the victim something to drink. However, the victim coughed violently and could not ingest anything. Thinking that things were dangerous to the victim, the parent took the victim to a local hospital. At 10 minutes after aspiration, the toy was removed by the physician. The victim had no sequela.</td></tr>
</table>

<table>
<tr><td>Case 5</td><td>Case of aspiration of a part of a toy</td><td>Aspirated object (Image)</td></tr>
<tr><td>Age (in months) of the victim</td><td>One year and ten months</td><td rowspan="4">
</td></tr>
<tr><td>Persons at the scene</td><td>Grandmother, mother, older brother (age of five years), younger brother (victim)</td></tr>
<tr><td>Time of occurrence</td><td>Around evening, November to December, 2014</td></tr>
<tr><td colspan="2">Overview</td></tr>
<tr><td colspan="3">The victim was playing next to the older brother playing with a toy in the living room. The mother was preparing for dinner in the kitchen and sometimes saw what the children were doing over an open kitchen. Because the older brother suddenly loudly said, “He ate something!” the mother rushed to the victim and looked into his mouth. He appeared to have gotten slightly teary, but did not choke. There was nothing in his mouth and he expelled nothing even when patted on his back. The mother called an ambulance after consultation with the grandmother. During transportation by ambulance, the victim expelled a piece of rubber by virtue of the intervention by emergency personnel. The victim had no sequela.</td></tr>
</table>

Case 6	Case of aspiration of a part of a doll	Aspirated object (Image)
Age (in months) of the victim	Two years	
Persons at the scene	Father, mother, older brother (age of five years), younger sister (victim)	
Time of occurrence	Between 15:00 and 18:00, September 2015	
Overview		
When the parents were relaxed on a sofa in the living room (approximately five meters away from the scene) watching TV, the older brother and victim were playing with toys spread in a Japanese-style room continuous with the living room. When the parents heard an unusual cry and went near the victim, the older brother said, “She has eaten a toy.” The victim was distressfully holding her neck. The father told her to cough to spontaneously expel it, patted her back, and turned her upside down and patted her back, but could not take it out. The father put his finger into the victim’s mouth to induce vomiting and a blue part of a toy (5 to 10 mm in length, approximately 3 mm in width, and approximately 3 mm in thickness) came out with vomitus. It was a part of a doll approximately 30 mm in length and flat and gently curved in shape and made of material like an inelastic rubber. Although it took two to three minutes for the victim to expel the part after aspiration, the victim then acted normally and had no sequela.		

Case 7	Case of aspiration of a part (a rubber spherical object) of a toy	Aspirated object (Image)
Age (in months) of the victim	Two years and three months	
Persons at the scene	Mother, child (victim)	
Time of occurrence	Around 20:00, June 2016	
Overview		
The victim was playing with block toys, sitting in the front of the TV in the living room. The mother was cooking in a kitchen (approximately two to three meters away from the scene), with her back to the child. When the mother suddenly heard the child crying and rushed to the victim, the victim blushed in the face and was giving slightly choking coughs. The mother immediately lifted the child up and patted the area between the victim’s neck and back several times and a toy part approximately 10 mm in diameter (a rubber spherical object) came out from the victim’s mouth. The victim had no sequela.		

4.2. Questionnaire Survey among Toy-related Enterprises

A questionnaire survey was conducted among toy-related enterprises to determine efforts to ensure safety of toys and whether information on accidents was available. In addition, these enterprises, mainly those that responded to the questionnaire survey, were interviewed on recurrence prevention measures that the enterprises took.

4.2.1. Method of Survey

For the survey, a questionnaire was sent to 500 toy-related enterprises (manufacture, wholesale, retailing, and import)[51] that were located throughout Japan.

4.2.2. Survey Results

(1) Number of Respondents

Number of respondents: 175 of 500 enterprises (rate of respondents: 35%)
Number of respondents excluded: 19 enterprises
Number of valid respondents: 156 of 500 enterprises (rate of respondents: 31%)

(2) Attributes of Enterprises Providing Valid Responses

The 156 enterprises providing valid responses were distributed by industry as follows: “manufacturing industry,” 46% (72 enterprises); “wholesale industry,” 24% (38 enterprises); “retailing industry,” 21% (32 enterprises); “import industry,” 8% (12 enterprises); and “Other” and “No response” combined, 1% (2 enterprises).

When they were classified by total sales for fiscal year 2015, enterprises with sales of “≥100,000,000 yen and <500,000,000 yen” accounted for the largest proportion of 23% (36 enterprises), followed by those with sales of “≥1,000,000,000 yen and <5,000,000,000 yen” (16%, 25 enterprises), those with sales of “≥10,000,000 yen and <50,000,000 yen” (15%, 24 enterprises), and those with sales of “<10,000,000 yen” (13%, 20 enterprises) in this order.

When they were classified by proportion of their toys carrying the ST Mark,

[51] Enterprises that were affiliated with organizations such as the Japan Toy Association, Osaka Toy Industry Association, Tokyo Toy & Doll Cooperative Association, and Japan Plastic Toys Manufacturers’ Cooperative Association, as well as toy-related enterprises located throughout Japan that were selected from “i-Town page.”

enterprises having a proportion of "91% to 100%" represented the largest proportion of 24% (37 enterprises), followed by "1% to 10%" (17%, 26 enterprises), "81% to 90%" (10%, 15 enterprises), and "71% to 80%" (7%, 11 enterprises) in this order. The Japan Toy Associate was the organization with which the largest proportion of enterprises was affiliated (53%, 83 enterprises; multiple responses allowed), followed by Osaka Toy Industry Association (23%, 36 enterprises), Tokyo Toy & Doll Cooperative Association (19%, 29 enterprises), and Japan Plastic Toys Manufacturers' Cooperative Association (14%, 21 enterprises).

(3) Number of Cases of Accidents of Aspiration and Accidental Ingestion

(a) Number of cases of accidents

A question was asked about the number of cases of aspiration and accidental ingestion received from consumers for toys handled over the last three years and demonstrated that only one enterprise received only one case of aspiration. A total of 24 enterprises (15%) received at least one case of accidental ingestion, although 132 enterprises (85%) received no such information (Figure 43).

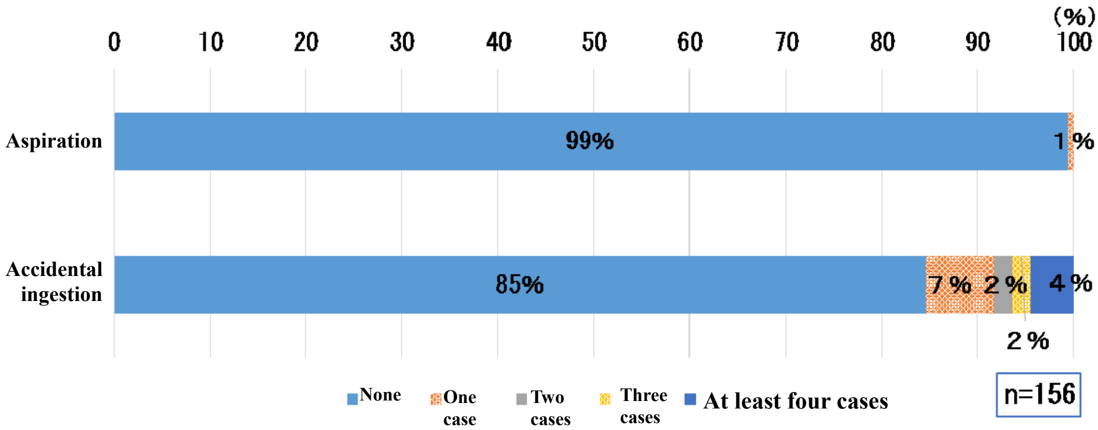


Figure 43. Number of cases of aspiration and accidental ingestion over the last three years

A question was asked about the type of toys that were reported to be aspirated or accidentally ingested by children and demonstrated that "parts other than magnets or batteries" were the most common type of toys (6 responses available) for accidental ingestion, followed by "small balls" (4 responses available), although no response was obtained for aspiration (Figure 44).

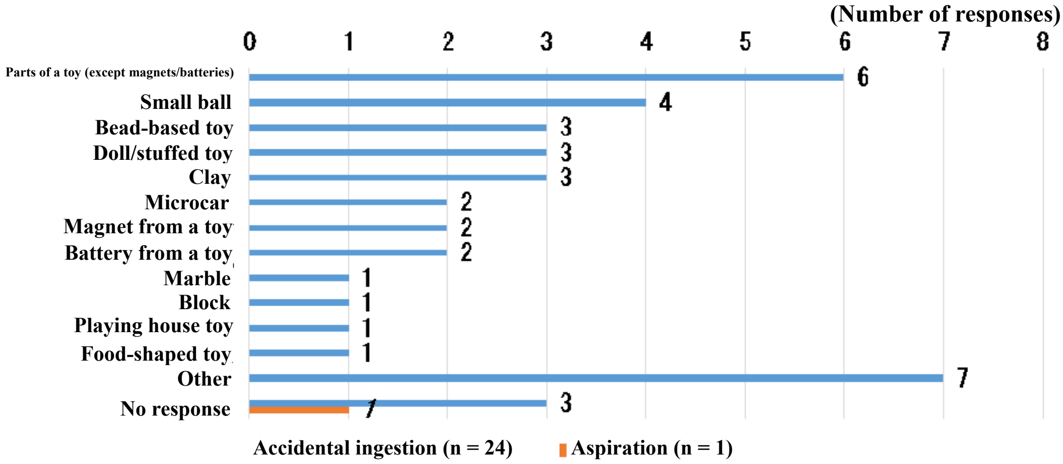


Figure 44. Type of toys reported to be aspirated or accidentally ingested by children

(4) Method for Determining Intended Ages

A question was asked about how to determine the intended ages for toys to be manufactured and sold and the following responses (open-ended description) were obtained:

- Intended ages are determined according to the stage of development of children. ISO/TR8124-8 Age determination guidelines[52] are consulted, as needed.
- Intended ages depend on the type of parts of toys.
- Intended ages are determined by the specifications of toys or how to play with toys and character traits of toys. Quality standards are established according to intended ages and toys are manufactured and sold after ensuring safety.
- Determined based on character traits, consumer questionnaire surveys, and opinions and sales performance of distributors, and ages of buyers of animations, games, and comics.
- Determined by reference to questionnaire surveys and results of experience events. Determined considering how to play with products and depth of understanding of packages and instructions for use.
- Intended ages are estimated based on the desired ability appropriate for the age in months and stage of development and verified and determined by using monitors.
- Determined in accordance with product specifications considering characters used for products and groups of their users. Many products are intended for children

[52] Guidelines for establishing the lower limit of the intended age of a toy.

aged eight years and older who are able to understand something, because users are required to understand precautionary statements.

• Because our products are faithful to the copyrighted creations, faithfully reproducing sharp shapes or edgy shapes is our strength. Therefore, the intended age is at the age of 15 years or more.

(5) Efforts to Ensure Safety of Toys

In response to the question about efforts to prevent aspiration/accidental ingestion, “using warning labeling” was the most common response, provided by 84 enterprises (54%), followed by “manufacturing products that can obtain the ST Mark” (65 enterprises, 42%) and “using PL graphical symbols (Figure 45)” (60 enterprises, 39%) (Figure 46).

Don’t put in the mouth

Figure 45. Example of PL graphical symbols[53]

[53] A graphical symbol (a registered trademark of the Japan Toy Association) that the Japan Toy Association created to communicate the meaning (intention) of warnings or cautions to children who cannot read letters well in a visual manner to direct more attention to risk by symbolizing the meaning (intention) of warnings or cautions and indicating the symbols as warnings or cautions. For products that do not bear the ST Mark, this graphical symbol is allowed to be used when an application for license is submitted as predetermined by the Japan Toy Association and is considered proper by the Japan Toy Association.

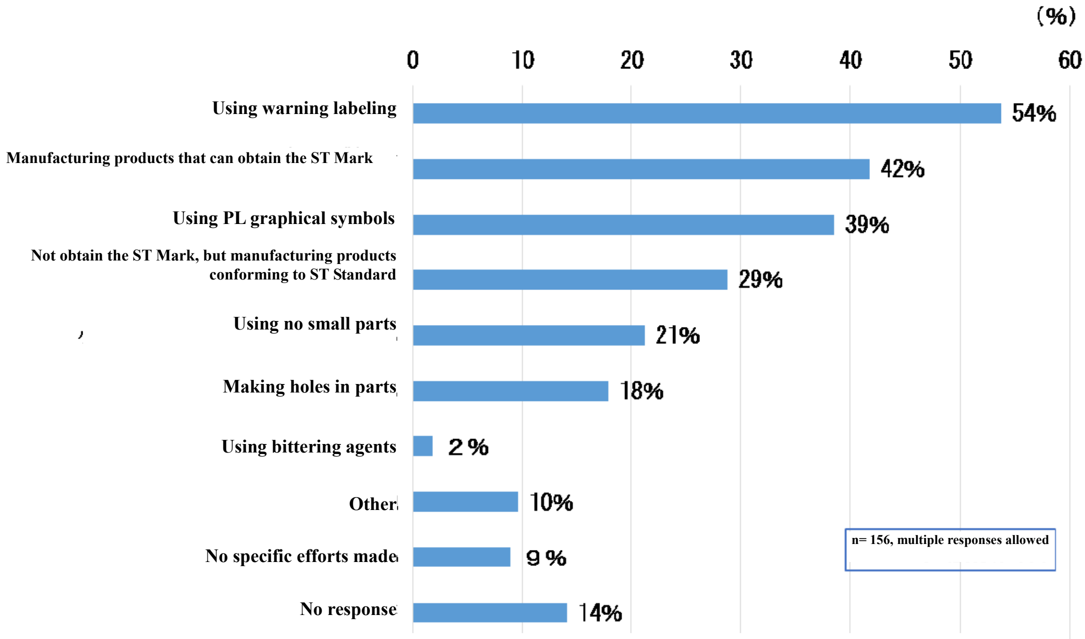


Figure 46. Efforts to prevent aspiration and accidental ingestion

A question was asked about what efforts should be made by administrative bodies, enterprises, and consumers to prevent aspiration and accidental ingestion and the following responses (open-ended description) were obtained:

- Enterprises should not only manufacture products conforming to ST Standard but also devise strategies such as making holes in parts to maintain an open airway and applying a bittering agent to make a child immediately expel an object even if the child puts the object in the mouth.
- A small company that imports small toys clearly indicates the intended age of 6 years and over on any products. Possible good measures include raising standards for products on which the intended age of 6 years and over is indicated and raising hurdles for customs clearing, such as submission of random samples.
- Administrative bodies should provide information to parents/guardians of an infant on an ongoing basis.
- It is good that domestic and overseas information on accidents is summarized as detailed information, including remedial measures, and can be made publicly available.
- Consumers should understand children's developmental characteristics of putting anything in the mouth and keep small parts, as well as toys, out of reach of

children.

- It appears that many parents/guardians who encounter accidental ingestion do not pay much attention to intended ages or warning labeling. Administrative bodies should provide public information that such indications are intended for avoidance of accidents.
- Unexpected accidents, including those caused by toys, inevitably occur, even though regulations are placed on manufacturers or products to prevent accidents. It is important that manufacturers and other enterprises, administrative bodies, and consumers make efforts to prevent accidents in a balanced manner. For example, manufacturers and other enterprises should sell products that are less likely to cause accidents, administrative bodies should post accident cases or risks on websites, etc. in an understandable way, and consumers should educate children.

4.2.3 Interview

A total of 10 toy-related enterprises that were affiliated with the Japan Toy Associate were interviewed on details of efforts to ensure safety. An overview of the results is provided below:

- Even if product tests for small parts are passed and the ST Standard is met, it does not make sense when the toys are broken into parts. Not only the small parts test, but also design and product tests considering possible associated types of accidents are performed.
- Not only conformity with the ST Standard but also unique quality standards are used. For example, even products intended for children aged three years and over are designed to maintain an open airway in case of swallowing by making 3-mm holes in small parts at least 10 mm in diameter or making the shape of toys corrugated.
- For food-shaped toys (intended for children aged three years and over), not only the small parts test, but also product tests applicable to toys intended for children under 18 months are performed.
- Product tests for small parts are verified for any intended age to implement countermeasures appropriate for the age and utilization status.
- Conformity with European standards for the safety of toy is ensured and unique add-on standards are put in place based on the awareness that products further above such standards need to be manufactured.

- In product tests for small parts, a test using the small parts cylinder and Accidental Ingestion Checker are both used.
- ST Standard is an important point for ensuring the safety of toys. However, it is probable that children play with toys in an unexpected manner and throw the toy to be broken into parts, potentially contributing to injuries or accidental ingestion. Therefore, it is important for preventing accidents due to toys to plan the design and product tests of toys attractive to children based on the observation of how children handle toys, as well as reports of the cause of previous accidents.
- For toys intended for children aged three years and over, the intended ages are determined with various possible scenarios in mind, such as these toys being given to children aged two years at home.
- Intended ages are indicated with large letters on a conspicuous location on the package or color-coded by age.

4.3. Questionnaire Survey among Educational/Childcare Facilities

A questionnaire survey was conducted among educational/childcare facilities to determine situations of the occurrence of aspiration of toys and efforts to prevent accidents.

4.3.1. Method of Survey

For the survey, a questionnaire was sent to 1,500 “kindergartens,” “licensed daycare centers,” “certified child care centers,” and “non-licensed daycare facilities”[54] which were located throughout Japan.

4.3.2. Survey Results

(1) Number of Respondents

[54] A total of 400 kindergartens (public and private), 400 licensed daycare centers (licensed nurseries, small-scale childcare business, domestic childcare business, childcare business at offices, kindergarten and daycare center cooperative type certified childcare centers, kindergarten type certified childcare centers, daycare center type certified childcare centers, and local discretion type certified childcare centers), and 700 non-licensed daycare facilities (local independent childcare facilities, baby hotels, and other non-licensed childcare facilities). These facilities were selected based on address books at various facilities throughout Japan with care to avoid geographical bias.

Number of respondents: 729 of 1,500 facilities (rate of respondents: 49%)
Number of respondents excluded: 25 facilities
Number of valid respondents: 704 of 1,500 facilities (rate of respondents: 47%)

(2) Attributes of Educational/Childcare Facilities Providing Valid Responses

The 704 educational/childcare facilities providing valid responses were distributed as follows: licensed daycare centers, 28% (199 facilities), the largest category, followed by kindergarten, 27% (190 facilities), other non-licensed daycare facility, 20% (140 facilities), and local independent childcare facilities, 10% (69 enterprises) in this order (Figure 47).

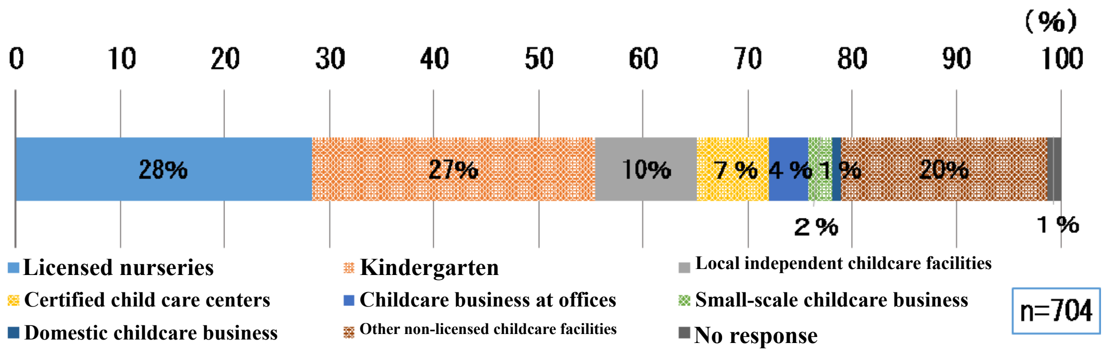


Figure 47. Disposition of educational/childcare facilities

When the 704 educational/childcare facilities were classified by number of staff, 25% of facilities (179) had 6 to 10 staff members, 20% (140 facilities) had 11 to 15 staff members, 19% (132 facilities) had 1 to 5 staff members, 13% (91 facilities) had 16 to 20 and ≥26 staff members, and 10% (71 facilities) had 21 to 25 staff members. When they were classified by number of children accepted, 25% of facilities (174) accepted 1 to 25 children, 20% (137 facilities) 26 to 50 children, 13% (92 facilities) 51 to 75 children, 13% (88 facilities) 76 to 100 children, 10% (67 facilities) 101 to 125 children, 6% (41 facilities) 126 to 150 children, 5% (35 facilities) 151 to 175 children, 2% (13 facilities) 176 to 200 children, and 8% (57 facilities) ≥201 children.

(3) Number of Cases of Aspiration

A question was asked about the occurrence of aspiration for 2015 and demonstrated that 4% of facilities (29 facilities) responded that “aspiration had occurred” (Figure

48).

A total of 29 facilities that responded that "aspiration had occurred" were asked about the group of products contributing to aspiration. The results showed that "food" was the most common (72%, 21 responses), followed by "toys" (17%, 5 responses) (Figure 49)

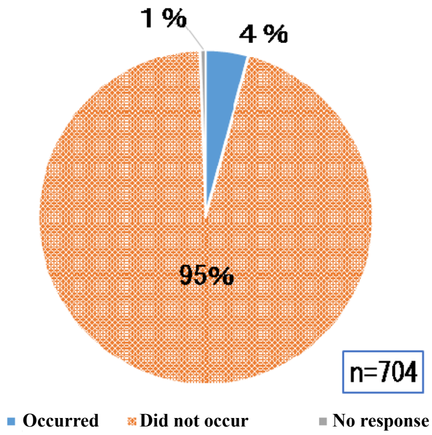


Figure 48. Presence/absence of occurrence of aspiration

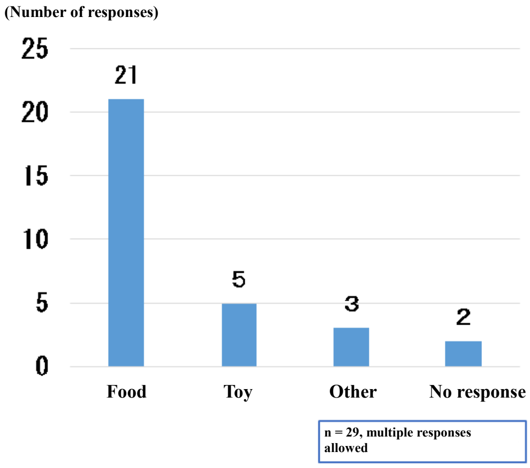


Figure 49. Product groups contributing to aspiration

In Figure 49, the types of aspirated toys (five responses) included "bead-based toy," "block and building block," "toy for playing house," "toy in the shape of food," and "doll and stuffed toy," each of which represented one response.

(4) Purchase of Toys

A question was asked about what educational/childcare facilities placed importance on when purchasing toys (the top three were chosen from a list of 11 options) and demonstrated that "safety" was the most common response, given by 97% (685 facilities), followed by "interest of children" (76%, 535 facilities) and "price" (45%, 315 facilities) (Figure 50).

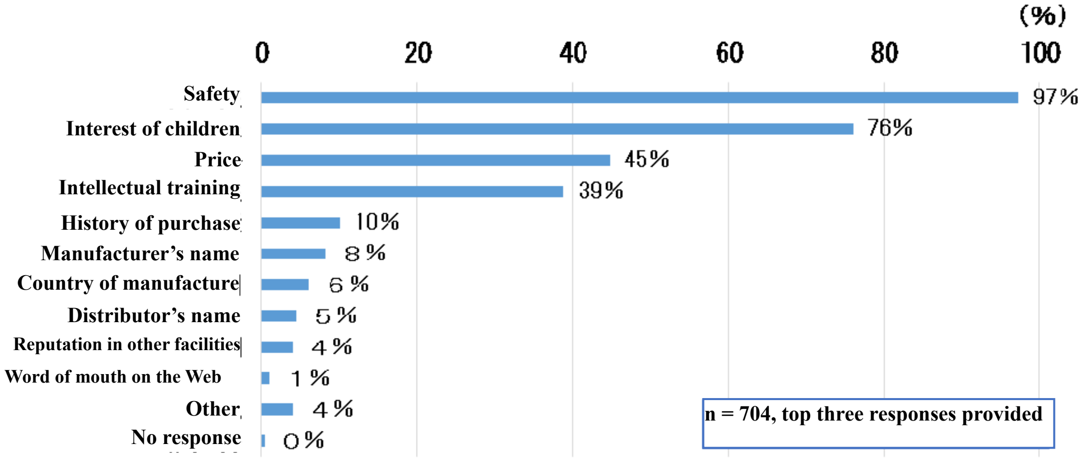


Figure 50. What importance is placed on when buying toys

A total of 685 facilities that responded that they placed importance on "safety" were asked about the basis for determining safety (the top three were chosen from a list of 13 options) and demonstrated that "shape of toys" was the most common response, given by 76% (520 facilities), followed by "size of toys" (73%, 499 facilities) and "mark on the package of toys" (49%, 336 facilities) (Figure 51).

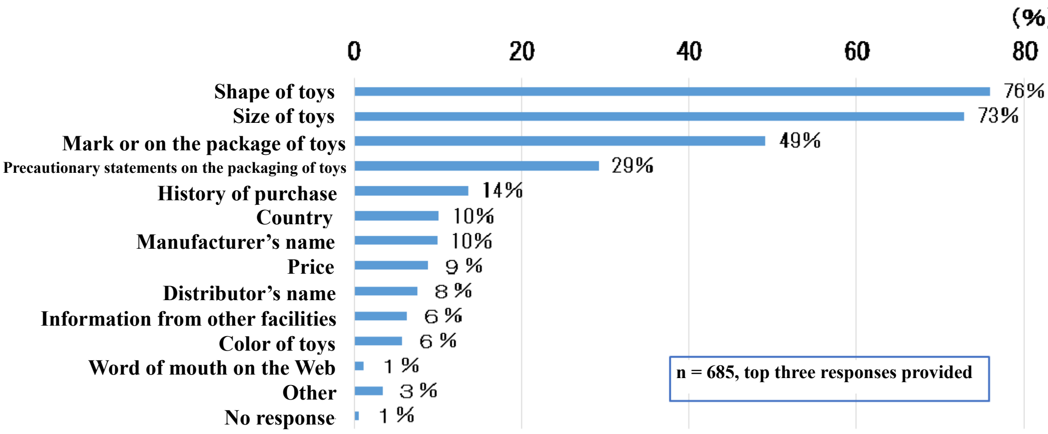


Figure 51. Basis for determining the safety of toys

A question was asked about what kind of management was practiced to prevent accidents of aspiration of toys and the following responses (open-ended description) were obtained:

- It is made sure that qualified personnel members are present, depending on age and development.
- The number of spherical toys passed to children is limited according to their hand dexterity and the number of balls is checked when putting them together.

- Objects smaller than Accidental Ingestion Ruler[55] are not let out of sight.
- Color, size, shape, material, strength, or places to be installed are considered.
- When toys are bought, responsible personnel and management check them for safety.
- Toys of sizes that allow them to enter the mouth, ear, or nose are not placed in places in which infants play.
- It is made sure that adults are present to watch young children when they play and that the number of accessories of toys is counted to check for any loss.
- Toys with incomplete parts, such as broken parts or missing parts, are not placed in front of children.
- There is a "Crisis Management Manual for Nurseries" in place. It is used because it specifies accidental ingestion and is accompanied by "Check List for Domestic Toys."
- Because of caring for children of mixed ages, toys containing small parts are allowed to be used after infants go home or after a circle is placed for partition.

(5) Responses to Accidents of Aspiration

A question was asked about the establishment of a manual for accidents of aspiration and demonstrated that among the 704 facilities, 56% responded that they had not established any manual for preventing and responding to aspiration accidents. In addition, 28% of facilities had an established manual for preventing and responding to aspiration accidents and 8% had an established for responding to aspiration accidents. An analysis by type of educational/childcare facilities showed that the greatest proportion of facilities responding that they had not established any manual for preventing and responding to aspiration accidents was observed for kindergarten (85%), followed by non-licensed daycare facility (48%) and licensed daycare centers (42%) in this order (Figure 52).

[55] As with Accidental Ingestion Checker (3.4.1), an educational tool developed by the Japan Family Planning Association to prevent aspiration or choking in children based on scientific values such as measurements of the mouth of infants. It is also used as a bookmark for the maternal and child health handbook.

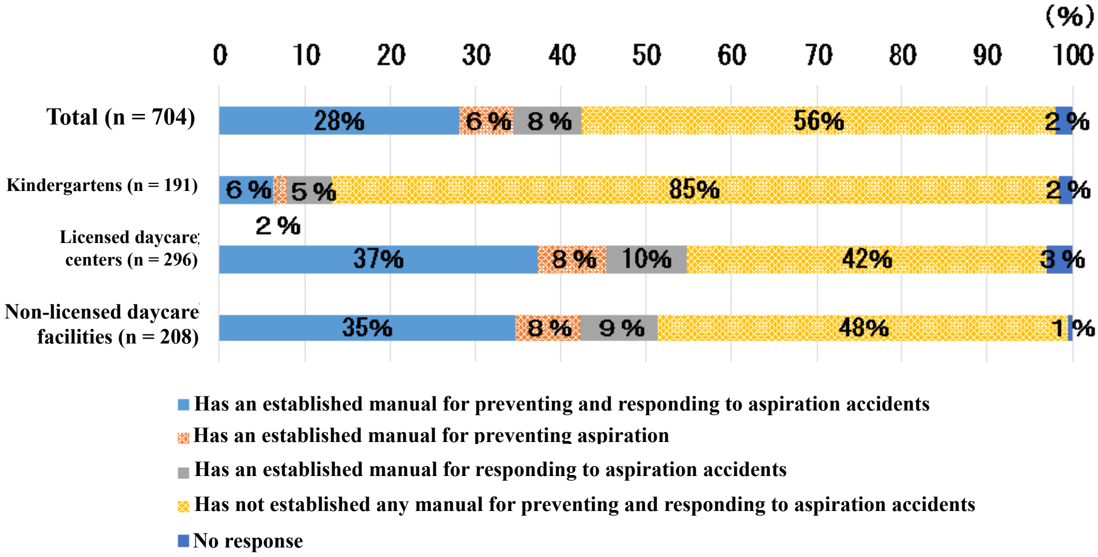


Figure 52. Establishment of a manual for aspiration accidents

A question was asked about the training to respond to aspiration accidents and demonstrated that 38% (264 facilities) responded that they provided such training. An analysis by type of facilities found that such training was provided in approximately 20% of kindergartens and approximately 40% of licensed daycare centers and non-licensed daycare facilities (Figure 53).

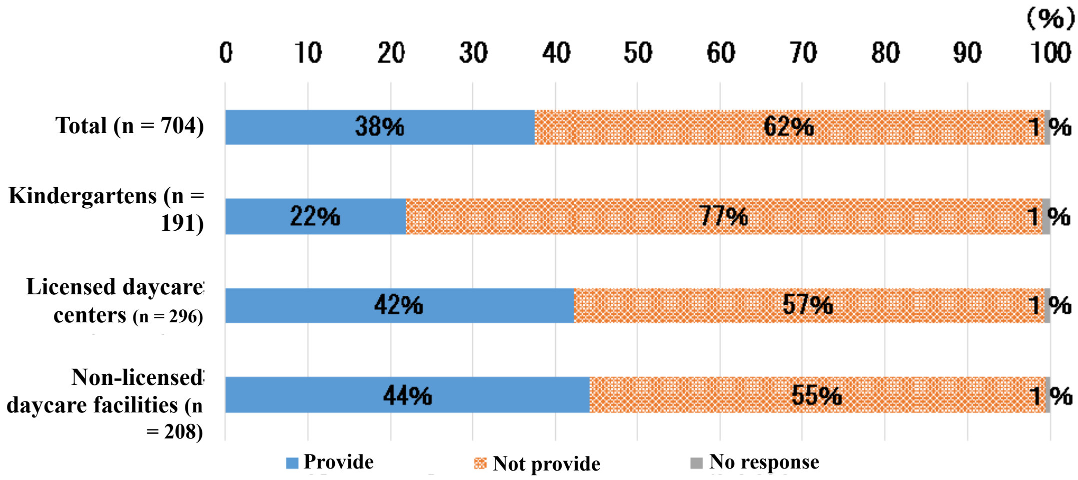


Figure 53. Training to respond to aspiration accidents

A total of 264 facilities responding that they provided training were asked about the frequency of training. The results showed that “approximately once a year” was the most common response, accounting for the majority (65%) of facilities, followed by “approximately once in 6 months” (17%) and “other” (7%) (Figure 54).

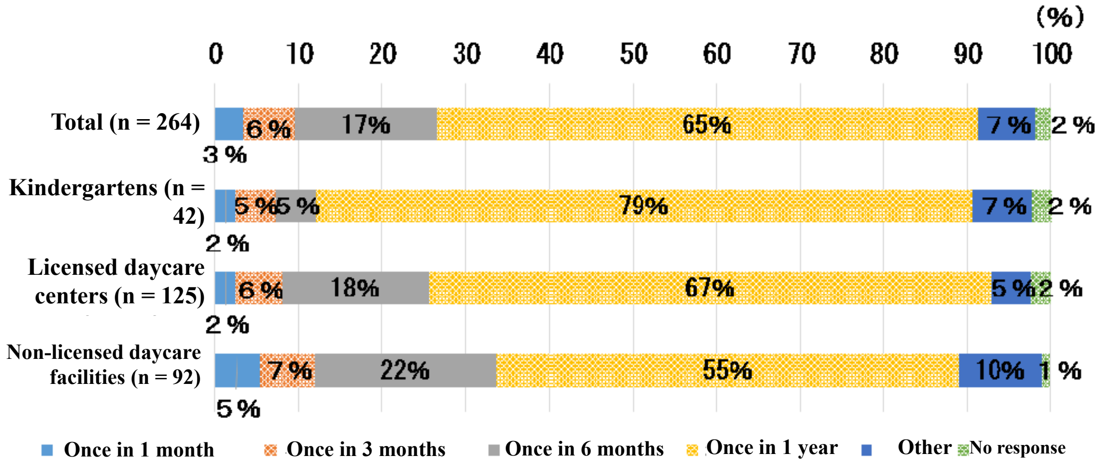


Figure 54. Frequency of training to respond to aspiration accidents

In addition, a total of 264 facilities responding that they provided training were asked about what kind of training they provided. The results showed that “back blow maneuver” was the most common response, given by 75% of facilities, followed by “artificial respiration” (74%) and “use of AEDs” (71%) (Figure 55).

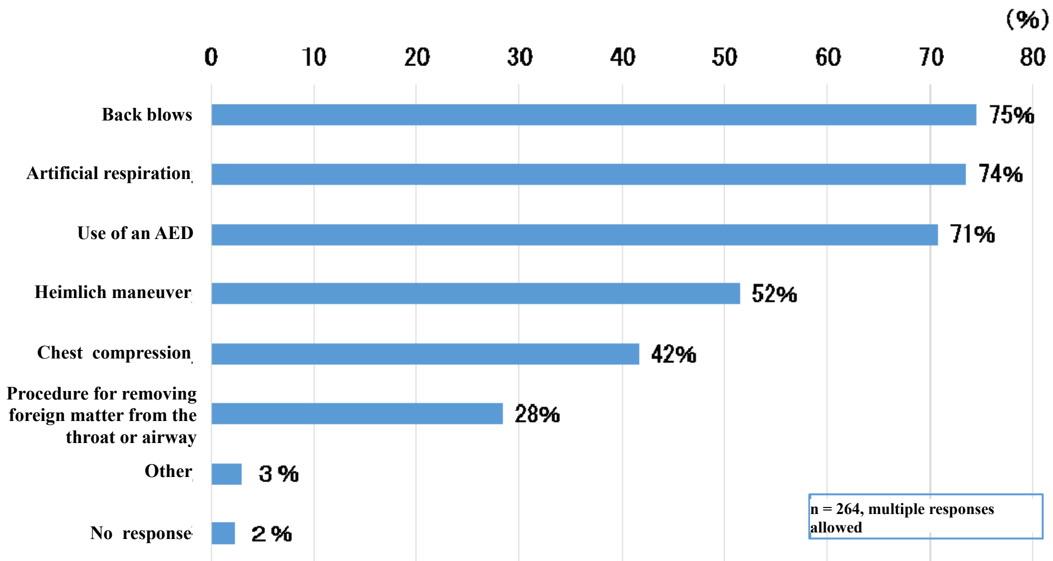


Figure 55. What kind of training do you provide?

4.4. Collection and Analysis of Data on Emergency Transportation

To further expand the investigation into actual conditions of airway obstruction accidents due to toys, data on emergency transportation in children (aged between 0 and 6 years) transferred by ambulance with aspiration and accidental ingestion were collected.[56] Among such data, cases of aspiration of toys were selected to analyze the number of cases, severity, and type and characteristics of aspirated toys.

4.4.1. Method of Investigation

With the cooperation of 10 fire departments located in special districts, ordinance-designated cities, and prefectural capitals in prefectures, data on emergency transportation between January 1, 2012 and December 31, 2015 were obtained from these fire departments and analyzed by the Investigation Commission.

4.4.2. Investigation Results

(1) Number of People Transferred by Ambulance with Aspiration and Accidental Ingestion of Toys

The number of people transferred by ambulance with aspiration and accidental ingestion between 2012 and 2015 for these 10 fire departments is shown (Table 8).

[56] Data were reviewed and classified into three categories of "aspiration," "accidental ingestion," and "other." Then, the "other" category was eliminated. The objects subject to analysis include toys and other objects such as food and tobacco.

Table 8. Number of people transferred by ambulance with aspiration and accidental ingestion for the fire departments (Unit: persons)

Fire department	Aspiration/accidental ingestion	Toy	
		Aspiration	Accidental ingestion
A	3, 897	69	314
B	449	7	31
C	412	3	47
D	300	5	25
E	276	3	24
F	272	6	19
G	208	1	12
H	190	0	18
I	124	1	3
J	89	2	3
Total	6, 217	97	496

(2) Disposition of Cases of Aspiration and Accidental Ingestion by Product

The disposition of cases of aspiration and accidental ingestion between 2012 and 2015 for these 10 fire departments is shown by product below. Food was the most common cause of cases of transportation by ambulance (24%), followed by tobacco (11%) and toys (9%) in this order (Figure 56).

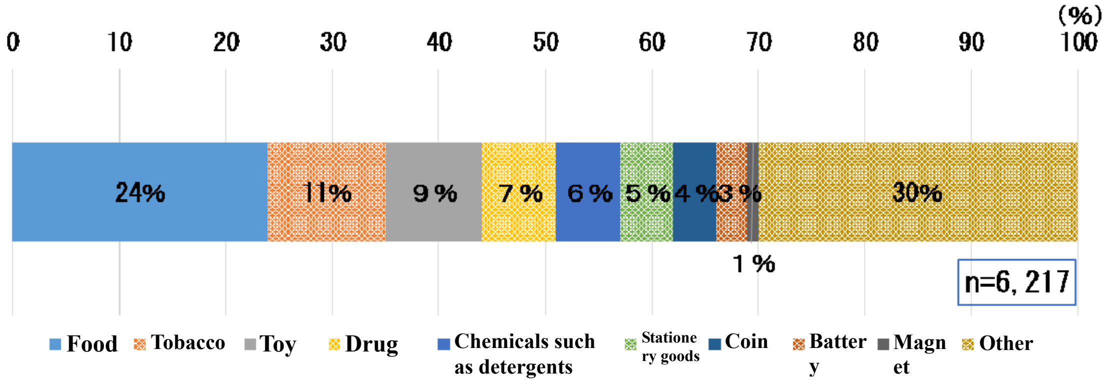


Figure 56. Disposition of cases of aspiration and accidental ingestion by product

(3) Aspiration of Toys

A total of 97 cases of aspiration of toys occurring between 2012 and 2015 were analyzed.

(a) Circumstances of children immediately before aspiration and intensity of symptoms

The circumstances of children immediately before aspiration and intensity of symptoms are shown in Table 9. Among the 97 cases, 41 cases described the circumstances of children immediately before aspiration, including “playing” in 23 cases, “holding a toy in the mouth” in 8 cases, “eating” in 7 cases, and “taking a bath” in 3 cases.[57]

Table 9. Circumstances of children immediately before aspiration and intensity of symptoms (Unit: persons)

Circumstances of children immediately before aspiration	Total	Intensity of symptoms		
		Mild	Moderate	Severe
Playing	23	23	0	0
Holding the toy in the mouth	8	7	1	0
Eating	7	5	0	2
Taking a bath	3	2	1	0
Unknown	56	46	8	2
Total	97	83	10	4

(b) Ages of children experiencing aspiration and intensity of symptoms

An analysis of the ages of children experiencing aspiration found that aspiration was the most common in children younger than one year and tended to decrease with increasing age. In addition, moderate and severe[58] symptoms tended to be more common in infants aged between 0 and 1 year (Figure 57)

[57] There was no description of the situation of children immediately before aspiration in 56 unknown cases.

[58] “Severe” disease refers to an intensity of injury requiring at least three weeks of hospitalization for treatment. “Moderate” disease refers to an intensity of injury that is not severe or mild. “Mild” disease refers to an intensity of injury requiring no hospitalization for treatment. (Fire and Disaster Management Agency “2016 edition of the current state of first-aid and rescue operations” (in Japanese))

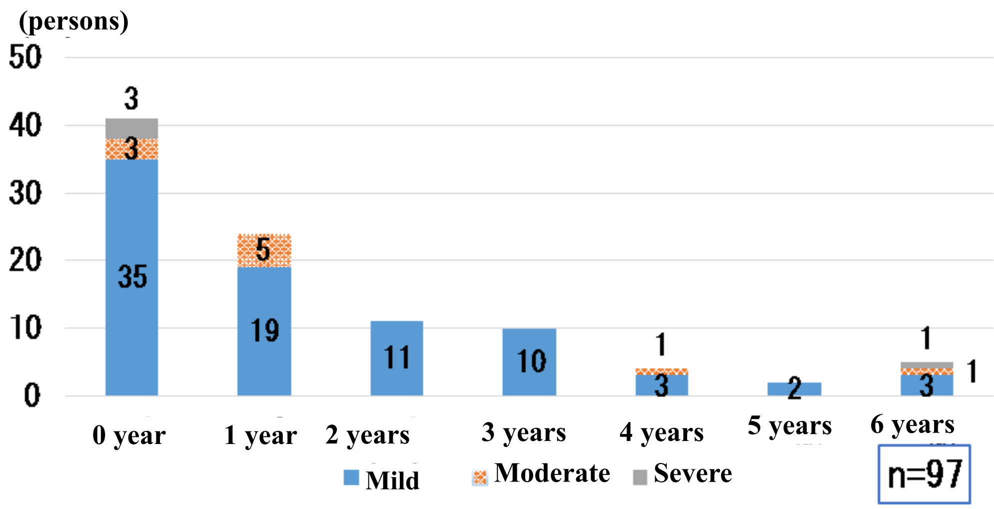


Figure 57. Ages of children experiencing aspiration and intensity of symptoms

(c) Size and shape of aspirated toys

Information was obtained from 17 of 97 cases of aspiration. Aspirated toys were not more than 30 mm in size in any case (Table 10).

Table 10. Size and shape (Unit: persons)

Size	Total	Shape		
		Flat object	Objects of the same size when viewed from any plane	Unknown
0～5mm	1	0	1	0
6～10mm	5	1	2	2
11～20mm	9	5	2	2
21～30mm	2	2	0	0
Unknown	80	—	—	—

Among the 17 cases with information available on size, 16 cases were mild in severity and 1 case was moderate in severity (with the relevant toy being 10 mm in diameter and 1 mm in thickness and flat in shape).

(d) Disposition of aspirated toys by product

"Toy (unspecified)" was the most common, followed by "part of a toy" and "block toy."

The toys responsible for severe cases included "toy (unspecified)," "block toy," "rubber ball," and "toy ring" (Figure 58).

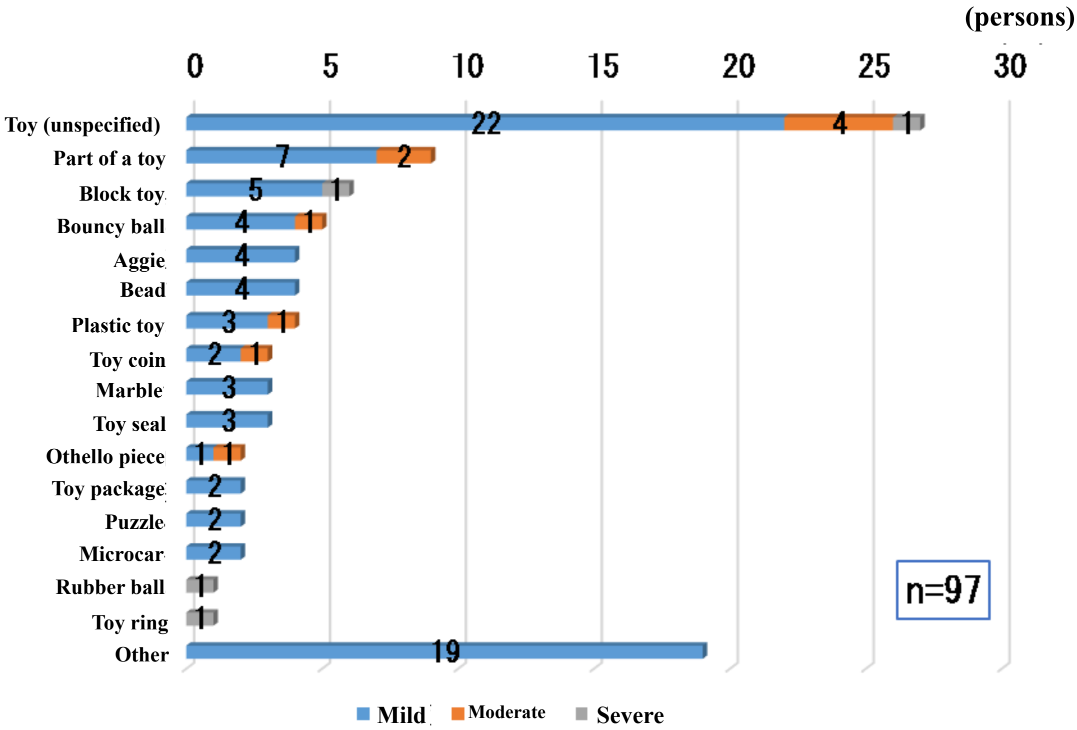


Figure 58. Number of cases of aspiration accidents by product

(e) Responses of parents/guardians in case of aspiration

A total of 14 of 97 cases of aspiration described responses of parents/guardians, including “scraping out the aspirated object” in six cases, the largest group, “back blow maneuver” in five cases, and “turning the victim upside down” in three cases. Two or more responses were taken in some cases.

Among the above 14 cases, four cases were moderate or greater in severity. The responses to these cases included “back blow maneuver” in two cases (with the Heimlich maneuver used in combination in one of them), “scraping out the aspirated object” in one case, and “opening the airway (unspecified)” in one case.

5. Analysis 2 (Computer Simulation)

Although airway obstruction accidents occur within the pharynx or larynx and thus cannot be directly observed or reproduced in experiments, virtual experiments (simulations[59]) can be performed on a computer. Therefore, simulations of airway obstruction caused by toys and airflow simulations were performed to determine the mechanism by which toys caused airway obstruction, the likelihood of choking among different shapes or sizes of toys, and the potential for avoidance of choking through giving the shapes of toys twists.

Swallow Vision®[60] was used for airway obstruction simulation. Swallow Vision® is a computer simulation system developed for elucidating the mechanisms of swallowing and aspiration. It provides the modeling of morphologies of the mouth, pharynx, larynx, esophagus, etc. and the modeling of swallowing movement based on medical CT images and videofluoroscopic images of swallowing.

5.1. Overview of Swallow Vision®

5.1.1. Three-dimensional Structures of Related Organs as Visualized with Swallow Vision® – Mechanism of Airway Obstruction

The three-dimensional structures of the related organs as visualized with Swallow Vision®[61] are shown in Figure 59.

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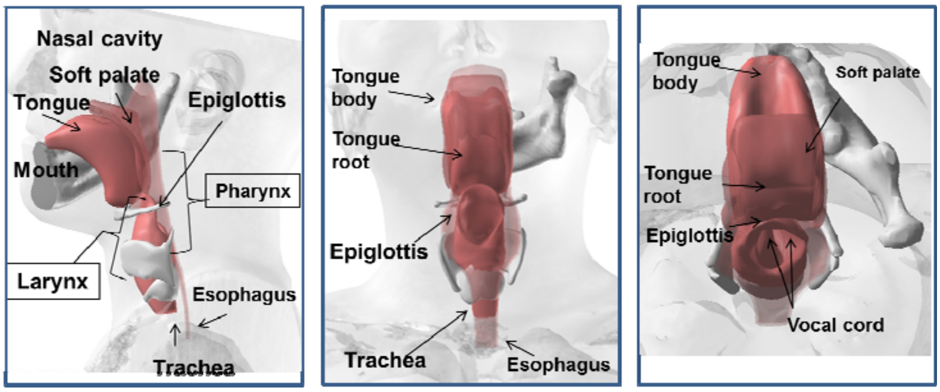
[59] A procedure in which structures, movements, and functions of a living body are mathematically represented to calculate and predict biological responses under varying conditions.

[60] Jointly developed by Meiji Co., Ltd. and Mr. Yukihiro Michiwaki, Director, Oral Surgery Division, Musashino Red Cross Hospital (an assigned expert member for investigation of this accident). This development is registered as patent (Patent No. 6060076) and Meiji Co., Ltd. is the patent holder. Swallow Vision is a registered trademark of Meiji Co. Ltd.

[61] A model of a 25-year-old healthy man used.



Lateral view Dorsal view Superior view

Figure 59. Three-dimensional structures of the related organs, including the mouth, pharynx, larynx, and esophagus

The tongue is inverted L-shaped and is horizontal in the mouth (tongue body) and vertical on the side of the pharynx (tongue root). Transport of a solid from the mouth to the pharynx requires active movement of the tongue and the solid rapidly drops with the force of gravity after entering the pharynx. The lower end of the tongue root is the epiglottis.

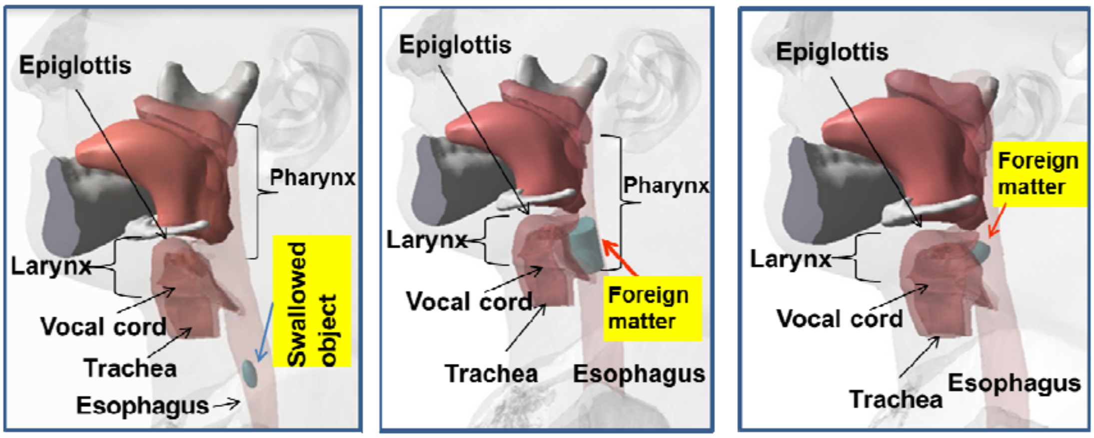
The epiglottis serves as a breakwater at the entrance to the larynx (laryngeal aperture) to prevent anything other than air from entering the larynx. During swallowing, it covers the laryngeal aperture to prevent solids and other objects from entering the larynx.

Vocal cords are folds located in the larynx. During breathing or speech, air passes through an opening formed between the vocal cords on both sides (the glottis). The glottis is smaller in size than the laryngeal aperture and leads to the trachea.

5.1.2 Swallowing and Asphyxiation Visualized by Swallow Vision®

The movement to transport food from the mouth through the pharynx to the esophagus is called swallowing (Figure 60 (a)). During passage of food through the pharynx, food does not enter the larynx, because the epiglottis and vocal cords function to close the laryngeal aperture. In other words, all food is transported to the esophagus while the laryngeal aperture is closed. The tongue is mainly responsible for transporting food to the pharynx and gravity force and pharyngeal muscles are mainly responsible for transporting food in the pharynx to the esophagus. The movement of the tongue, that is, “transportation of food to the pharynx,” is voluntary. On the other hand, the post-pharyngeal movement, that is, “transportation of food in the pharynx to the esophagus,” is involuntary.

Asphyxiation is a condition of lack of oxygen (hypoxia) resulting from airway obstruction and associated inability to breathe. It can be classified into pharyngeal obstruction-type asphyxiation and laryngeal obstruction-type asphyxiation, according to the area with obstruction.



(a) Swallowing (b) Pharyngeal obstruction-type (c) Laryngeal obstruction-type

Figure 60. Aspiration and choking shown with Swallow Vision®

Figure 60(b) shows an example of pharyngeal obstruction-type choking. Foreign matter is located in the pharynx and the laryngeal aperture is covered by the epiglottis, leading to inability to breathe. Figure 60(c) shows an example of laryngeal obstruction-type choking. Although the pharynx is open, foreign matter blocks the larynx, leading to inability to breathe.

5.2. Airway Obstruction Simulation

5.2.1. Overview of the Procedure for Performing Airway Obstruction Simulation

Airway obstruction simulation requires numerical models of the living body and toys. Numerical models of the living body were created based on CT images of the head and neck of a 9-month-old boy without swallowing disorder and videofluoroscopic images of swallowing of a 9-month-old girl, because these images were available. Numerical models of toys were created under conditions of shape, size, hardness, coefficient of friction, coefficient of restitution, etc. established considering results from the questionnaire survey on parents/guardians, reported cases in "Injury Alert," etc. A total of 48 sessions of airway obstruction simulation, as listed below, were performed using these integrated living body and numerical models and the results of simulation analysis were finally visualized in a three-dimensional way on a computer.

(a) Sphere: 10 sessions
(b) Hemisphere: 7 sessions
(c) Ellipse[62]: 7 sessions (3 sessions in a rugby ball shape and 4 sessions in a peanut shape)
(d) Cuboid: 2 sessions
(e) Cube: 6 sessions
(f) Block toy: 3 sessions
(g) Marble-shaped toy: 5 sessions
(h) Pacifier-shaped toy: 8 sessions

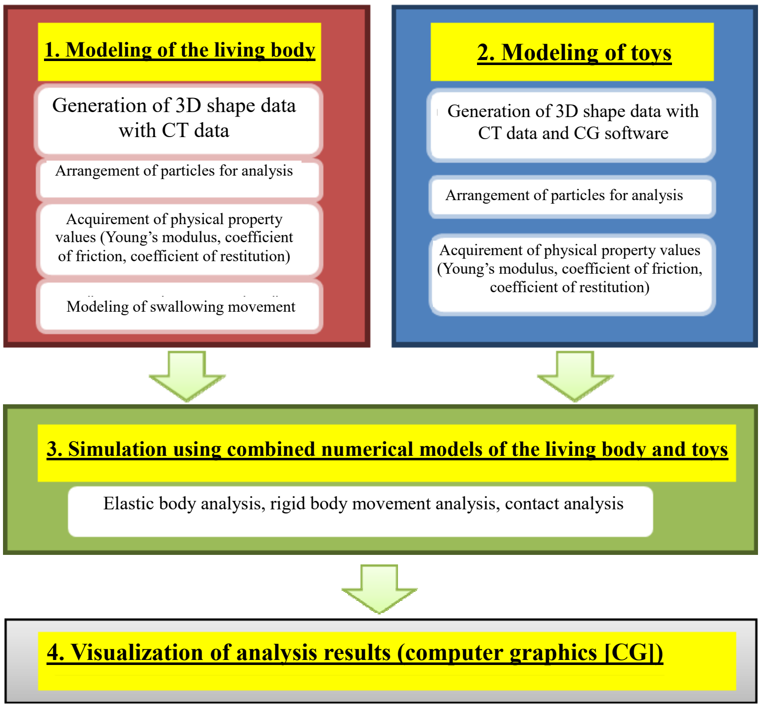


Figure 61. Process of airway obstruction simulation

5.2.2 Results of Airway Obstruction Simulation Analysis

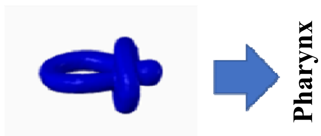
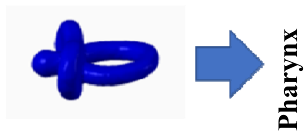
A list of the results of airway obstruction simulation using numerical models of the toys is provided in Table 14.

[62] The rugby ball shape and peanut shape are different in the length of the minor axis. The minor diameter of the rugby ball shape is longer than that of the peanut shape.

The results of 48 sessions of airway obstruction simulation analysis using integrated numerical models of the living body and the toys were classified into four categories of choking risk in accordance with the criteria described in Table 13. The results indicated that 32, 11, 4, and 1 sessions of simulation showed “high,” “intermediate,” “low,” and “no” risk of choking, respectively.
An analysis by shape indicated that spheres showed “high” and “intermediate” risk of choking in 9 and 1 of the 10 sessions, respectively, hemispheres showed “high,” “intermediate,” and “low” risk of choking in 4, 2, and 1 of the 7 sessions, respectively. The rugby ball shape, peanut shape, cuboid, and cube showed “high” choking risk in all the 3, 4, 2, and 6 sessions, respectively. Block toys showed “high” and low” choking risk in 2 and 1 of the 3 sessions, marble shapes showed “intermediate,” “low,” and “no” risk of choking in 2, 1, and 1 of the 5 sessions, respectively, and pacifier-shaped toys showed “high” and “intermediate” choking risk in 2 and 6 of the 8 sessions, respectively.
A description of terms is shown in Table 11 below:

Table 11. Description of terms

Term	Description
Coefficient of friction	A coefficient that describes the slipperiness of a toy on the mucosal surface of the tongue or pharynx. A larger value indicates less slipperiness. Because infants secrete much saliva, “notably slippery conditions” and “slippery conditions” were used.
Coefficient of restitution	A coefficient that describes how much a toy bounces back from a living body. A larger value indicates greater bounce. This coefficient was set with reference to values from experiments using the porcine tongue mucosa.
Respiratory position	The position of an organ such as the mouth, pharynx, larynx, and esophagus during respiration. Figure 59 shows the respiratory position of each organ.
Rigid body	An object that is assumed to undergo no change in volume or shape even if an adequately large force is applied. An ordinary solid may often be seen as a rigid body.
Elastic body	A general term for objects used to discuss deformation within their elastic limit. It may refer to objects with especially large elastic limits, like rubber.
Young’s	A ratio of tensile or compressive stress to distortion in the direction

modulus	of the stress (stretch or shrinkage per unit length) in a solid. A constant specific to a substance. To evaluate the effect of the hardness of a toy, choking risk was analyzed with simulations under different conditions of elasticity.
Major diameter and minor diameter	Of the two axes of an ellipse, the longer one is called the major axis and its length is called the major diameter. The shorter one is called the minor axis and its length is called the minor diameter.
Tongue and palate	The tongue and the soft palate.
Below the pharynx	The pharynx, esophagus, and larynx for the purpose of this investigation.
Laryngeal aperture	Opening into the larynx.
Drag	A force that acts on the surface of an object to interfere with the movement of the object. Its component perpendicular to the movement is normal force and a horizontal component is often force of friction.
Front-back direction	For the pacifier-shaped toy, it refers to the orientation shown in the right figure. 
Back-front direction	For the pacifier-shaped toy, it refers to the orientation shown in the right figure. 
Liquid	For the purpose of this section, it refers to liquid having an viscosity of 100 mPa•s (equivalent to condensed milk).

For the purpose of the simulations, the criteria for the degree of obstruction of the pharyngeal and laryngeal cavities the criteria for choking risk were defined as shown below (Table 12 and Table 13):

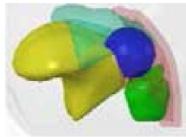
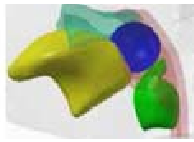
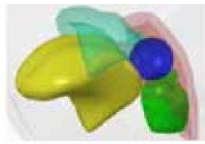
Table 12. Degree of obstruction of the pharyngeal cavity and laryngeal cavity

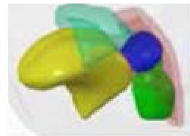
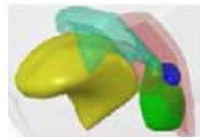
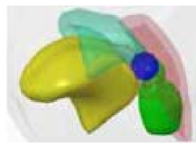
Degree of obstruction	Meaning
Complete obstruction	A state in which no air seems to go in and out of the pharyngeal or laryngeal cavity and which leads to serious disease in a short time.
Almost complete obstruction	A state in which some air goes in and out, but with its volume being probably not sufficient to maintain respiration.
Semi-obstruction	A state in which air can go in and out with its volume being probably sufficient to maintain respiration for a relatively long time.
Open	A state in which the pharyngeal or laryngeal cavity is almost completely or completely open and in which breathing disorder leading to hypoxia probably does not occur.

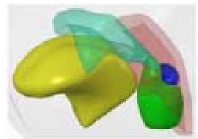
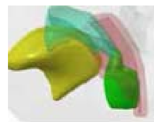
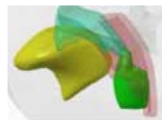
Table 13. Criteria for choking risk

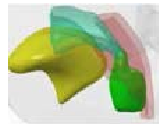
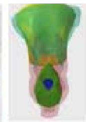
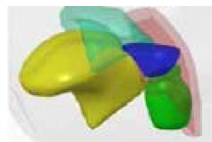
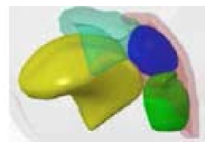
Choking risk	Criteria
High	The pharyngeal or laryngeal cavity is completely or almost completely obstructed. The pharyngeal cavity and the laryngeal cavity or laryngeal aperture are semi-obstructed at the same time.
Intermediate	The pharyngeal cavity, laryngeal cavity, or laryngeal aperture is semi-obstructed.
Low	A toy is lodged in the mouth.
No	Swallowing is possible.

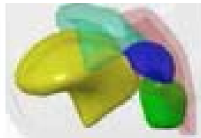
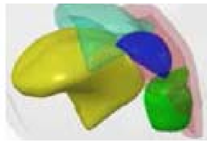
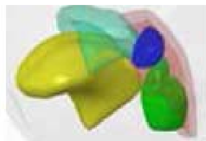
Table 14. List of the results of airway obstruction simulation analysis

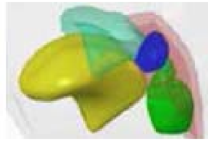
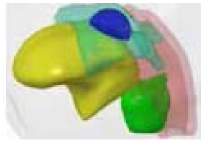
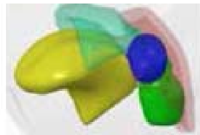
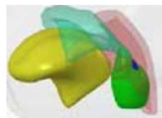
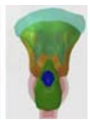
Shape	No.	Conditions					Result	Risk	Image
		Size	Hardn ess	Coefficient of friction	Coefficient of restitution	Other			
Sphere	1	Diameter 20 mm	Rigid	0.05	0.03	Analysis was prematurely discontinued due to increases in elasticity and normal force	- Stayed in the pharyngeal cavity. - Obstructed the pharyngeal cavity. - Applied pressure to the epiglottis from above. - Semi-obstructed the laryngeal aperture.	High	
Sphere	2	Diameter 18 mm	Rigid	0.05	0.03		- Stayed in the pharyngeal cavity. - Obstructed the pharyngeal cavity. - Applied pressure to the epiglottis from above. - Semi-obstructed the laryngeal aperture.	High	
Sphere	3	Diameter 15 mm	Rigid	0.05	0.03		- Stayed in the pharyngeal cavity. - Obstructed the pharyngeal cavity. Applied pressure to the epiglottis from above. - Almost completely	High	

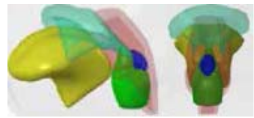
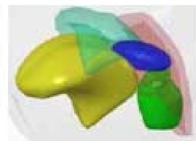
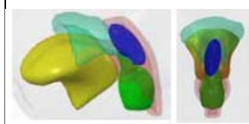
Shape	No.	Conditions					Result	Risk	Image
		Size	Hardness	Coefficient of friction	Coefficient of restitution	Other			
							obstructed the laryngeal aperture.		
Sphere	4	Diameter 15 mm	Elastic Young's modulus →20 kPa	0.05	0.03		- Stayed in the pharyngeal cavity. - Obstructed the pharyngeal cavity. - Applied pressure to the epiglottis from above. - Semi-obstructed the laryngeal aperture.	High	
Sphere	5	Diameter 10 mm	Rigid	0.05	1.0		- Stayed in the pharyngeal cavity. - Obstructed the pharyngeal cavity. - The laryngeal aperture was in a respiratory position. - Almost completely obstructed the pharyngeal cavity.	High	
Sphere	6	Diameter 10 mm	Rigid	Tongue/palate →0.1 Below pharynx →0.2	Tongue/palate →0.03 Below pharynx →0.8		- Stayed in the pharyngeal cavity. - Semi-obstructed the pharyngeal cavity. - The laryngeal aperture was in a	Intermediate	

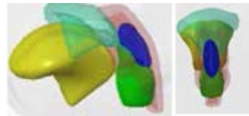
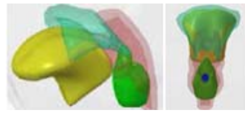
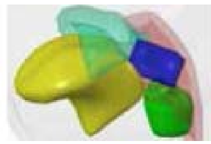
Shape	No.	Conditions					Result	Risk	Image
		Size	Hardness	Coefficient of friction	Coefficient of restitution	Other			
							respiratory position. - The laryngeal aperture was open.		
Sphere	7	Diameter 10 mm	Rigid	0.05	1.0	A change to the size of the uvula	- Stayed in the larynx. - Obstructed the laryngeal cavity. - Almost completely obstructed the pharyngeal cavity. - The epiglottis was in a respiratory position.	High	
Sphere	8	Diameter 6 mm	Rigid	0.05	1.0	A change to the size of the uvula The first of the two occasions of swallowing performed	- Stayed in the larynx. - Almost completely obstructed the laryngeal cavity. - The pharyngeal cavity was open. - The epiglottis was in a respiratory position.	High	 
Sphere	9	Diameter 6 mm	Rigid	0.05	1.0	A change to the size of the uvula The second of the two occasions of swallowing performed	- Stayed in the larynx. - Almost completely obstructed the laryngeal cavity. - The pharyngeal cavity was open. - The epiglottis was in a respiratory position.	High	 

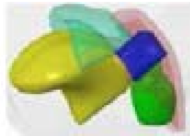
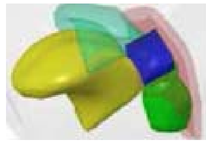
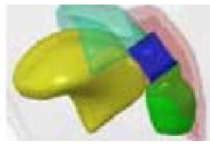
Shape	No.	Conditions					Result	Risk	Image
		Size	Hardness	Coefficient of friction	Coefficient of restitution	Other			
Sphere	10	Diameter 6 mm	Rigid	0.05	Tongue/palate →0.03 Below pharynx →0.8		- Stayed in the larynx. - Almost completely obstructed the laryngeal cavity. - The pharyngeal cavity was open. - The epiglottis was in a respiratory position.	High	 
Hemisphere	1	Diameter 20 mm	Rigid	0.05	0.03	Hemisphere turned downward The first of the two occasions of swallowing performed	- Stayed in the pharyngeal cavity. - Almost completely obstructed the pharyngeal cavity. - Applied pressure to the epiglottis. - Semi-obstructed the laryngeal aperture.	High	
Hemisphere	2	Diameter 20 mm	Rigid	0.05	0.03	Hemisphere turned downward The second of the two occasions of swallowing performed	Stayed in the pharyngeal cavity. - Almost completely obstructed the pharyngeal cavity. - Applied pressure to the epiglottis. - Semi-obstructed the laryngeal aperture.	High	

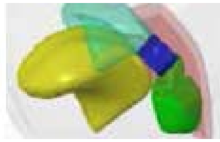
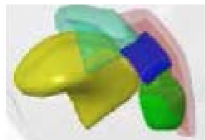
Shape	No.	Conditions					Result	Risk	Image
		Size	Hardness	Coefficient of friction	Coefficient of restitution	Other			
Hemisphere	3	Diameter 20 mm	Rigid	0.05	0.03	Hemisphere turned upward	- Stayed in the pharyngeal cavity. - Almost completely obstructed the pharyngeal cavity. - Applied pressure to the epiglottis. - Obstructed the laryngeal aperture.	High	
Hemisphere	4	Diameter 20 mm	Rigid	0.05	0.03	Hemisphere turned upward Passive movements of the epiglottis and soft palate	- Stayed in the pharyngeal cavity. - Almost completely obstructed the pharyngeal cavity. - Applied pressure to the epiglottis. - Almost completely obstructed the laryngeal aperture.	High	
Hemisphere	5	Diameter 15 mm	Rigid	0.05	0.03	Hemisphere turned downward The first of the two occasions of swallowing performed	- Stayed in the pharyngeal cavity. - Semi-obstructed the pharyngeal cavity. - The laryngeal aperture was open.	Intermediate	

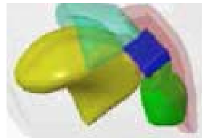
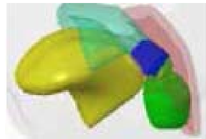
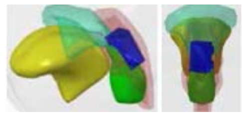
Shape	No.	Conditions					Result	Risk	Image
		Size	Hardness	Coefficient of friction	Coefficient of restitution	Other			
Hemisphere	6	Diameter 15 mm	Rigid	0.05	0.03	Hemisphere turned downward The second of the two occasions of swallowing performed	- Stayed in the pharyngeal cavity. - Semi-obstructed the pharyngeal cavity. - The laryngeal aperture was open.	Intermediate	
Hemisphere	7	Diameter 15 mm	Rigid	0.05	0.03	Hemisphere turned upward	- Could not swallow - Stayed in the mouth.	Low	
Ellipse (rugby ball shape)	1	Major diameter →23 mm Minor diameter →14 mm	Rigid	0.05	0.03		- Stayed in the pharyngeal cavity. - Almost completely obstructed the pharyngeal cavity. - Applied pressure to the epiglottis from above. - Semi-obstructed the laryngeal aperture.	High	
Ellipse (rugby ball shape)	2	Major diameter →11.5 mm Minor diameter	Rigid	Tongue/palate →0.1 Below pharynx →0.2	Tongue/palate →0.03 Below pharynx →0.8	The first of the two occasions of swallowing performed	- Stayed in the larynx. - Almost completely obstructed the laryngeal cavity. - The pharyngeal cavity was open.	High	 

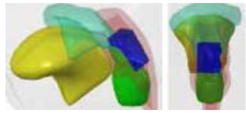
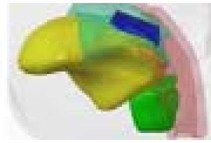
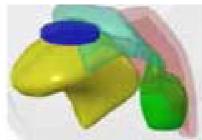
Shape	No.	Conditions					Result	Risk	Image
		Size	Hardness	Coefficient of friction	Coefficient of restitution	Other			
		→7 mm					- The epiglottis was in a respiratory position.		
Ellipse (rugby ball shape)	3	Major diameter →11.5 mm Minor diameter →7 mm	Rigid	Tongue/palate →0.1 Below pharynx →0.2	Tongue/palate →0.03 Below pharynx →0.8	The second of the two occasions of swallowing performed	- Stayed in the larynx. - Almost completely obstructed the laryngeal cavity. - Almost completely obstructed the pharyngeal cavity. - The epiglottis was in a respiratory position.	High	
Ellipse (peanut shape)	4	Major diameter →23 mm Minor diameter →10 mm	Rigid	Tongue/palate →0.1 Below pharynx →0.2	Tongue/palate →0.03 Below pharynx →0.8		- Stayed in the pharyngeal cavity. - Semi-obstructed the pharyngeal cavity. - Applied pressure to the epiglottis from above. - Semi-obstructed the laryngeal aperture.	High	
Ellipse (peanut shape)	5	Major diameter →23 mm Minor diameter →10 mm	Rigid	Tongue/palate →0.1 Below pharynx →0.2	Tongue/palate →0.03 Below pharynx →0.8	Only active movement of the soft palate after swallowing	- Stayed in the pharyngeal cavity. - Semi-obstructed the pharyngeal cavity. - Semi-obstructed the laryngeal aperture.	High	

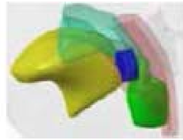
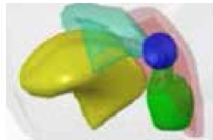
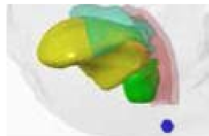
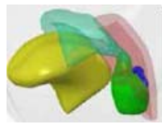
Shape	No.	Conditions					Result	Risk	Image
		Size	Hardness	Coefficient of friction	Coefficient of restitution	Other			
Ellipse (peanut shape)	6	Major diameter →23 mm Minor diameter →10 mm	Elastic Young's modulus →20 kPa	Tongue/palate →0.1 Below pharynx →0.2	Tongue/palate →0.03 Below pharynx →0.8		- Stayed in the pharyngeal cavity. - Semi-obstructed the pharyngeal cavity. - Semi-obstructed the laryngeal aperture.	High	
Ellipse (peanut shape)	7	Major diameter →11.5 mm Minor diameter →5 mm	Rigid	Tongue/palate →0.1 Below pharynx →0.2	Tongue/palate →0.03 Below pharynx →0.8		- Stayed in the larynx. - Almost completely obstructed the laryngeal cavity. - The pharyngeal cavity was open. - The epiglottis was in a respiratory position.	High	
Cuboid	1	Depth→10 mm Width→10 mm Height→15 mm	Rigid	0.05	0.03	The first of the two occasions of swallowing performed	- Stayed in the pharyngeal cavity. - Semi-obstructed the pharyngeal cavity. - Applied pressure to the epiglottis from above. - Obstructed the laryngeal aperture.	High	

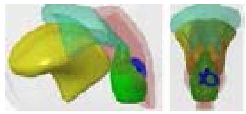
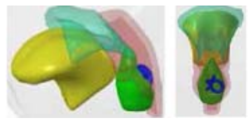
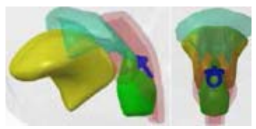
Shape	No.	Conditions					Result	Risk	Image
		Size	Hardness	Coefficient of friction	Coefficient of restitution	Other			
Cuboid	2	Depth→10 mm Width→10 mm Height→15 mm	Rigid	0.05	0.03	The second of the two occasions of swallowing performed	- Stayed in the pharyngeal cavity. - Almost completely obstructed the pharyngeal cavity. - Applied pressure to the epiglottis from above. - Semi-obstructed the laryngeal aperture.	High	
Cube	1	Diagonal 20 mm (11.6 mm/side)	Rigid	0.05	0.03		- Stayed in the pharyngeal cavity. - Almost completely obstructed the pharyngeal cavity. - Applied pressure to the epiglottis from above. - Semi-obstructed the laryngeal aperture.	High	
Cube	2	Diagonal 18 mm (10.4 mm/side)	Rigid	0.05	0.03		- Stayed in the pharyngeal cavity. - Almost completely obstructed the pharyngeal cavity. - Applied pressure to the epiglottis from	High	

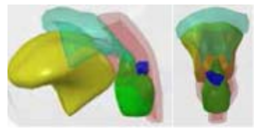
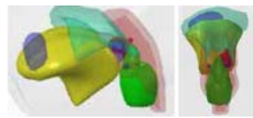
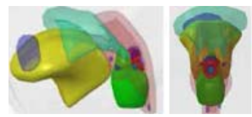
Shape	No.	Conditions					Result	Risk	Image
		Size	Hardness	Coefficient of friction	Coefficient of restitution	Other			
							above. - Semi-obstructed the laryngeal aperture.		
Cube	3	Diagonal 15 mm (8.7 mm/side)	Rigid	0.05	0.03		- Stayed in the pharyngeal cavity. - Semi-obstructed the pharyngeal cavity. - Applied pressure to the epiglottis from above. - Semi-obstructed the laryngeal aperture.	High	
Cube	4	Diagonal 20 mm (11.6 mm/side)	Elastic Young's modulus →20 kPa	0.05	0.03		- Stayed in the pharyngeal cavity. - Almost completely obstructed the pharyngeal cavity. - Applied pressure to the epiglottis from above. - Semi-obstructed the laryngeal aperture.	High	

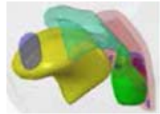
Shape	No.	Conditions					Result	Risk	Image
		Size	Hardness	Coefficient of friction	Coefficient of restitution	Other			
Cube	5	Diagonal 18 mm (10.4 mm/side)	Elastic Young's modulus →20 kPa	0.05	0.03		- Stayed in the pharyngeal cavity. - Almost completely obstructed the pharyngeal cavity. - Applied pressure to the epiglottis from above. - Semi-obstructed the laryngeal aperture.	High	
Cube	6	Diagonal 15 mm (8.7 mm/side)	Elastic Young's modulus →20 kPa	0.05	0.03		- Stayed in the pharyngeal cavity. - Semi-obstructed the pharyngeal cavity. - Applied pressure to the epiglottis from above. - Semi-obstructed the laryngeal aperture.	High	
Block toy	1	Depth→8 mm Width→9.5 mm Height→16 mm	Rigid	0.05	0.03		- Stayed in the pharyngeal cavity. - Semi-obstructed the pharyngeal cavity. - The epiglottis was in a respiratory position. - Almost completely obstructed the	High	

Shape	No.	Conditions					Result	Risk	Image
		Size	Hardness	Coefficient of friction	Coefficient of restitution	Other			
							laryngeal aperture.		
Block toy	2	Depth→8 mm Width→9.5 mm Height→16 mm	Rigid	0.05	0.03	A change to the tongue movement	- Stayed in the pharyngeal cavity. - Semi-obstructed the pharyngeal cavity. - The epiglottis was in a respiratory position. - Almost completely obstructed the laryngeal aperture.	High	
Block toy	3	Width→8 mm Length→9.5 mm Height→16 mm	Rigid	Tongue/palate →0.1 Below pharynx →0.2	Tongue/palate →0.03 Below pharynx →0.8		- Could not swallow. - Stayed in the mouth.	Low	
Marble shape	1	Diameter →30 mm Thickness →3.2 mm	Rigid	0.05	0.03		- Could not swallow. - Stayed in the mouth.	Low	
Marble shape	2	Diameter →20 mm Thickness →1.6 mm	Rigid	0.05	0.03		- Could not swallow. - Stayed in the mouth.	Low	

Shape	No.	Conditions					Result	Risk	Image
		Size	Hardness	Coefficient of friction	Coefficient of restitution	Other			
Marble shape	3	Diameter →11.6 mm Thickness →5.4 mm	Rigid	0.05	0.03	The first of the two occasions of swallowing performed	- Stayed in the pharyngeal cavity. - Semi-obstructed the pharyngeal cavity. - The epiglottis was in a respiratory position. - The laryngeal aperture was open.	Intermediate	
Marble shape	4	Diameter →11.6 mm Thickness →5.4 mm	Rigid	0.05	0.03	The second of the two occasions of swallowing performed	- Stayed in the pharyngeal cavity. - Semi-obstructed the pharyngeal cavity. - The epiglottis was in a respiratory position. - The laryngeal aperture was open.	Intermediate	
Marble shape	5	Diameter →5.8 mm Thickness →1.3 mm	Rigid	0.05	0.03		- Swallowed.	-	
Pacifier-shaped toy	1	Length→11 mm Width→10 mm Breadth→	Rigid	Tongue/palate →0.1 Below pharynx	Tongue/palate →0.03 Below pharynx	Front and back in this order	- Stayed in the pharyngeal cavity. - The pharyngeal cavity was open. - The epiglottis was in	Intermediate	 

Shape	No.	Conditions					Result	Risk	Image
		Size	Hardness	Coefficient of friction	Coefficient of restitution	Other			
		2 mm ~ 6 mm		→0.2	→0.8		a respiratory position. - Semi-obstructed the laryngeal aperture.		
Pacifier-shaped toy	2	Height→11 mm Depth→10 mm Width→2 mm ~ 6 mm	Rigid	Tongue/palate →0.1 Below pharynx →0.2	Tongue/palate →0.03 Below pharynx →0.8	Front and back in the reverse order The first of the two occasions of swallowing performed	- Stayed in the pharyngeal cavity. - The pharyngeal cavity was open. - The epiglottis was in a respiratory position. - Semi-obstructed the laryngeal aperture.	Intermediate	
Pacifier-shaped toy	3	Height→11 mm Depth→10 mm Width→2 mm ~6 mm	Rigid	Tongue/palate →0.1 Below pharynx →0.2	Tongue/palate →0.03 Below pharynx →0.8	Front and back in the reverse order The second of the two occasions of swallowing performed	- Stayed in the pharyngeal cavity. - The pharyngeal cavity was open. - The epiglottis was in a respiratory position. - Semi-obstructed the laryngeal aperture.	Intermediate	
Pacifier-shaped toy	4	Height→11 mm Depth→10 mm Width→2 mm ~ 6 mm	Rigid	Tongue/palate →0.1 Below pharynx →0.2	Tongue/palate →0.03 Below pharynx →0.8	Front and back in the reverse order Swallowing at a tilt of 45 degrees	- Stayed in the pharyngeal cavity. - The pharyngeal cavity was open. - The epiglottis was in a respiratory position. - Semi-obstructed the laryngeal aperture.	Intermediate	

Shape	No.	Conditions					Result	Risk	Image
		Size	Hardness	Coefficient of friction	Coefficient of restitution	Other			
Pacifier-shaped toy	5	Height→11 mm Depth→10 mm Width→2 mm ~ 6 mm	Rigid	Tongue/palate →0.1 Below pharynx →0.2	Tongue/palate →0.03 Below pharynx →0.8	Swallowing with the object in an inverted orientation present in the larynx	- Stayed in the pharyngeal cavity. - The pharyngeal cavity was open. - The epiglottis was in a respiratory position. - Semi-obstructed the laryngeal aperture.	Intermediate	
Pacifier-shaped toy	6	Height→11 mm Depth→10 mm Width→2 mm ~ 6 mm	Rigid	Tongue/palate →0.1 Below pharynx →0.2	Tongue/palate →0.03 Below pharynx →0.8	Swallowing with liquid The first of the two occasions of swallowing performed	- Stayed in the pharyngeal cavity. - Semi-obstructed the pharyngeal cavity. - The epiglottis was in a respiratory position. - The laryngeal aperture was open.	Intermediate	
Pacifier-shaped toy	7	Height→11 mm Depth→10 mm Width→2 mm ~ 6 mm	Rigid	Tongue/palate →0.1 Below pharynx →0.2	Tongue/palate →0.03 Below pharynx →0.8	Swallowing with liquid The second of the two occasions of swallowing performed	- Stayed in the pharyngeal cavity. - Semi-obstructed the pharyngeal cavity. - The epiglottis was in a respiratory position. - Almost completely obstructed the laryngeal aperture.	High	

Shape	No.	Conditions					Result	Risk	Image
		Size	Hardness	Coefficient of friction	Coefficient of restitution	Other			
Pacifier-shaped toy	8	Height→11 mm Depth→10 mm Width→2 mm ~ 6 mm	Rigid	Tongue/palate →0.1 Below pharynx →0.2	Tongue/palate →0.03 Below pharynx →0.8	Swallowing of liquid with the object present in the pharynx	- Stayed in the pharyngeal cavity. - Semi-obstructed the pharyngeal cavity. - The epiglottis was in a respiratory position. - Almost completely obstructed the laryngeal aperture.	High	 

5.3 Airflow Simulation

One possible method to prevent asphyxiation even under the condition of obstruction by a toy is giving the shape of a toy twists, including making holes in a toy to establish an air passage. Therefore, simulations were performed to determine whether such twists avoided asphyxiation.

5.3.1 Overview of the Procedure for Performing Airflow Simulation

With an object representing a toy placed in the space between the mouth and trachea of a shape representing the living body, airflow from the mouth and nasal cavity through the trachea was calculated by computer simulation.
The shape of the living body was created using shape data from the 9-month-old boy used for airway obstruction simulation (Figure 62).

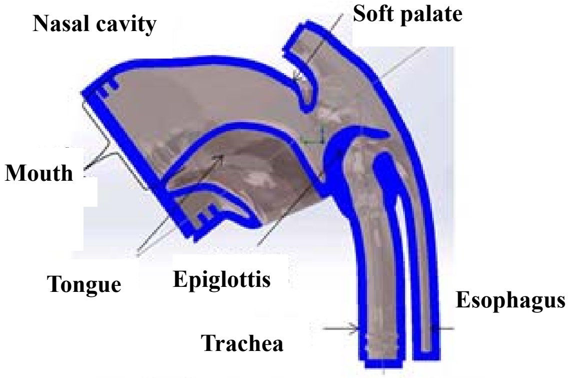


Figure 62 Shape data from a 9-month-old boy (section from the right side)

A sphere with a diameter of 20 mm that was found to pose “high” risk of pharyngeal obstruction-type choking based on the results of airway obstruction simulation was created as an object representing a toy. As a twist given to the shape of a toy, holes penetrating in three directions that were at right angles to one another were made (Figure 63).

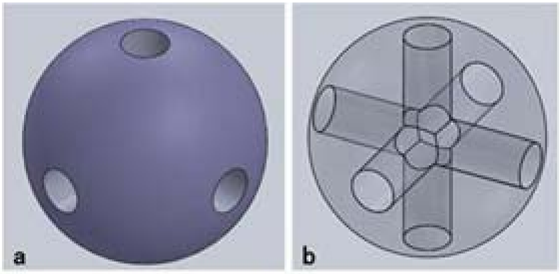


Figure 63. Image of a sphere 20 mm in diameter having holes (each 4 mm in diameter) made (left) and image showing the structure of the holes with a translucent external surface (right)

In addition, polyhedrons (a cube and a regular dodecahedron) in which a gap is potentially likely to be formed than in spheres were also created. For a comparison with a sphere 20 mm in diameter, they were designed so that the longest diagonal line was 20 mm for either shape (Figure 64).

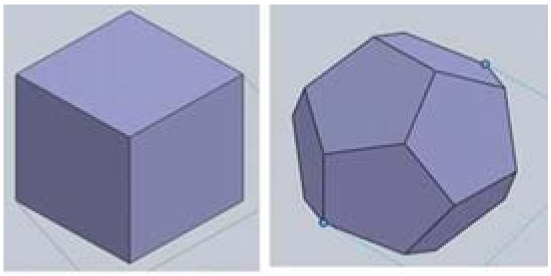


Figure 64. Cube and regular dodecahedron each with the longest diagonal line of 20 mm

5.3.2 Analysis in the Open State

Prior to verification of the state of obstruction by a toy, suction pressure, etc. in the open state without any obstruction was calculated. The results showed that the suction pressure in the open state was 31.09 Pa, indicating that air flowed in from the mouth at a rate of 57.537 mL/s and from the nasal cavity at a rate of 22.439 mL/s.

5.3.3 Setting of the Position of Obstruction and Orientation of Toys

In the space between the mouth and the trachea of a toy representing the living body, positions of obstruction by a toy were established in three points within the pharynx (Figure 65). A position posterior (dorsal) to the uvula[63] was set as P1 to reproduce

[63] The U-shaped tip of the soft palate, which is located closest to the tongue.

pressure on the epiglottis, a position 5 mm down toward the trachea from P1 was set as P2 to reproduce more pressure on the epiglottis, and a position 5 mm toward the mouth from P1 was set as P3 to reproduce shallow obstruction (Figure 66[64]).

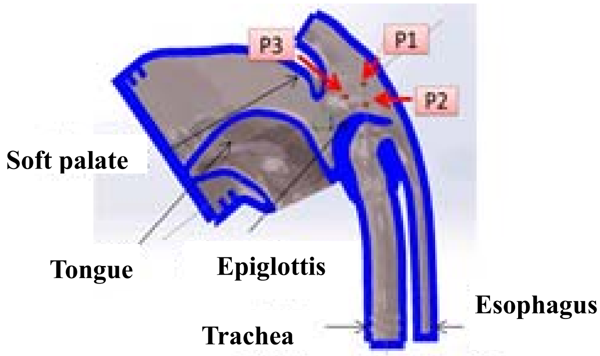


Figure 65. Positions of obstruction

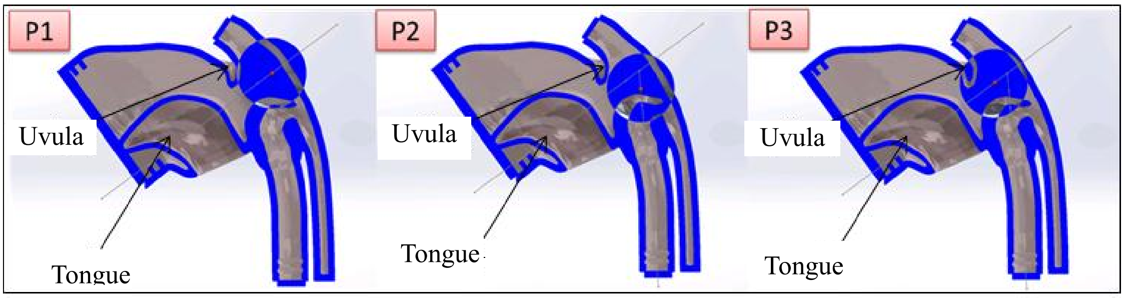


Figure 66. Spheres 20 mm in diameter placed in the positions of obstruction

The orientation of a spherical toy was first set so that the axes of the holes in two directions coincided with the median plane and the axis of the hole in the other direction was horizontal to the transverse plane. Calculation was then performed, changing the orientation at intervals of five degrees in a longitudinal direction. Analysis was performed in a total of 18 different orientations between 0 (initial position) and 90 degrees so that the same shape as that at the initial position was obtained at the time when a toy was turned by 90 degrees.

For polyhedrons, the orientation was first set so that the longest diagonal line coincided with the median plane. Calculation was then performed, changing the orientation at intervals of five degrees to obtain the same shape as that at the initial position, as with sphere. Analysis for polyhedrons was performed in a total of 36 different orientations

[64] Because the shapes of the living body and toys are not deformed, interfering areas are overlapped in the simulation. For example, in the case of obstruction by a toy at P2, the results have to be interpreted with the assumption that posterior compression is exerted on the posterior wall of the pharynx and downward compression is exerted on the epiglottis.

between 0 and 180 degrees (Figure 67).

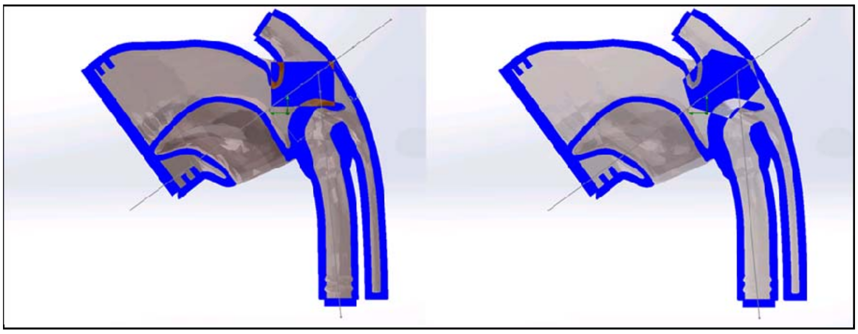


Figure 67. Polyhedrons placed in P3 (left: cube, right: regular dodecahedron)

5.3.4 Results of Airflow Simulation Analysis

(1) Effects of Shape

(a) Cube (regular hexahedron)

In the cube, airflow was found in all of the 36 positions (100%) between 0 and 180 degrees (Figure 68).

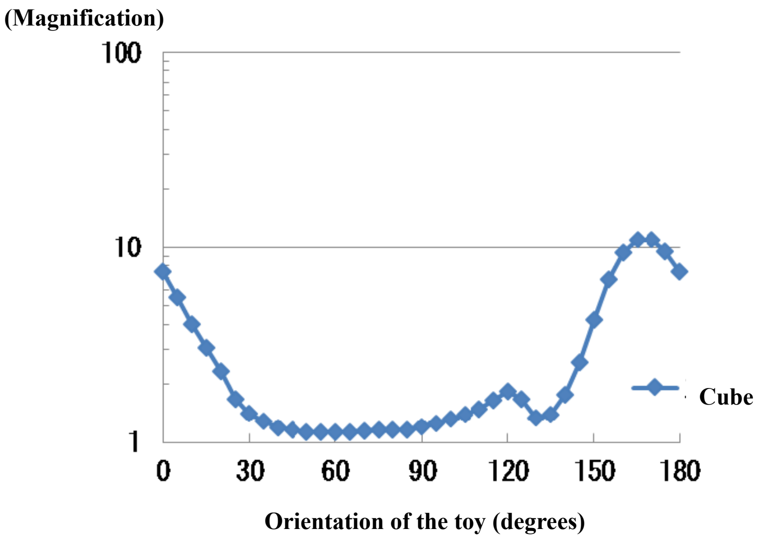


Figure 68. Suction pressure during obstruction by the cube (magnification ratio relative to the open state)

In addition, the magnification ratio of suction pressure[65] relative to the suction pressure in the open state was not more than 10 fold in almost all positions. It is

[65] The pressure necessary for suction at a suction flow rate set as an analysis condition.

highly possible that complete obstruction would be avoided even when a cube was lodged in the pharynx. A pathline diagram at 50 degrees with the smallest suction pressure is shown (Figure 69).

The results found that a cube was less likely to cause complete obstruction than a sphere, probably due to a large difference between the longest diagonal line and the shortest diagonal line of a cube. It is probable that a space was left even when the cube was lodged in the pharynx.[66]

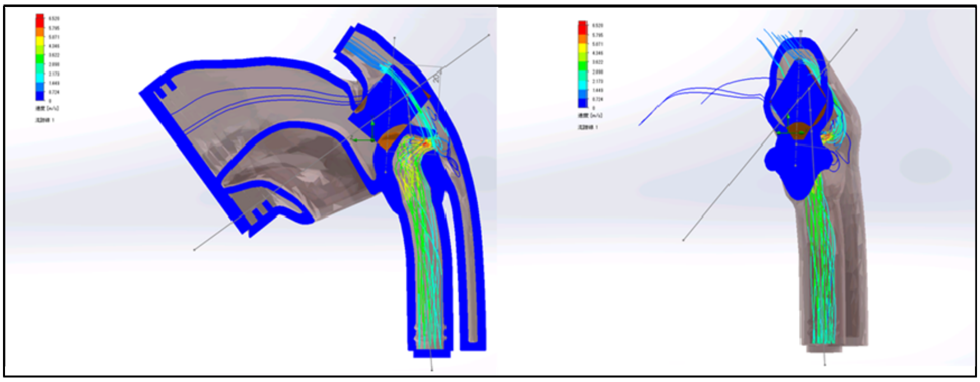


Figure 69. Pathline diagram in the orientation with the smallest suction pressure in the cube
(Left: cross section from the right side, right: coronal cross section)

(b) Regular dodecahedron

Airflow was found in 11 of the 36 points (31%) between 0 and 180 degrees. In addition, the magnification ratio of suction pressure relative to the suction pressure in the open state was not less than 60 fold in all positions except 1 position. The smallest suction pressure was 14-fold of the suction pressure in the open state (Figure 70). The regular dodecahedron is more likely to cause obstruction than the cube, because it was closer to a sphere than the cube.

[66] The results of the airway obstruction simulation analyses showed that the cube was assessed as posing a “high” risk of choking, due to differences in the methodology or purpose between these simulations; the airway obstruction simulation was to qualitatively assess choking risk and the airflow simulation was to quantitatively assess the degree of pharyngeal obstruction as measured by suction pressure.

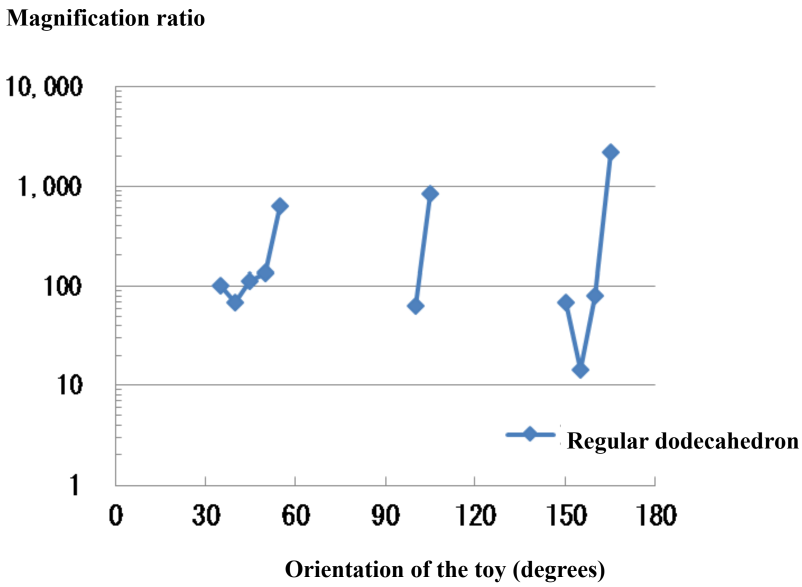


Figure 70. Suction pressure during obstruction by the regular dodecahedron (magnification ratio relative to the open state)

(2) Effects of the Twist of Making Holes

(a) Sphere without holes

First, a sphere 20 mm in diameter without holes was used to determine whether it caused complete obstruction in P1 to P3. The results showed that complete obstruction was not caused in P1 with airflow found only from the mouth at a suction pressure of 766.7 Pa.[67] This is probably due to the structure of the pharyngeal cavity characterized by being having a relatively large space, leaving small spaces even if a sphere is lodged in a relatively higher part of the pharyngeal cavity, such as P1. A pathline diagram in P1 shown in Figure 71 is provided.

[67] A unit of pressure. The condition in which force of 1 N (Newton) acts per 1 m^2.

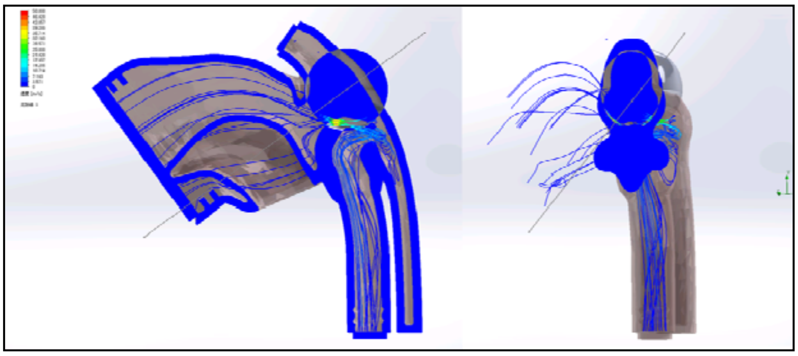


Figure 71. Results of the analysis of the ball without holes in P1
(Left: cross section from the right side, right: coronal cross section)

On the other hand, no inflow of air occurred due to complete obstruction of the pharynx in P2 (where the sphere was pushed into a lower part of the pharyngeal cavity) and P3 (where the center of the sphere was located near uvula). This is probably due to a narrower space near the epiglottis or below the uvula than that of the pharyngeal cavity. Therefore, analyses of spheres with holes were performed in P2 and P3.

(b) Spheres with holes located in P2

For either sphere with 3-mm holes or 4-mm holes, no inflow of air was found in any orientation analyzed. This was probably because the spheres were pushed down to obstruct the boundary between the larynx and esophagus, leading to the blockade of the passage of air from the pharyngeal cavity to the larynx. In addition, in an actual living body, it is probable that pharyngeal obstruction and laryngeal obstruction simultaneously occur due to additional obstruction of the laryngeal aperture caused by pressure on the epiglottis.

These results suggested that, when pushed down deep into the pharyngeal cavity, toys that caused pharyngeal obstruction might pose a high risk of causing complete obstruction of the respiratory tract regardless of the presence of holes in the toys (Figure 72).

It should be noted that spheres with 2-mm holes, which were smaller than 3-mm holes, were not analyzed, because no airflow might occur, as observed above.

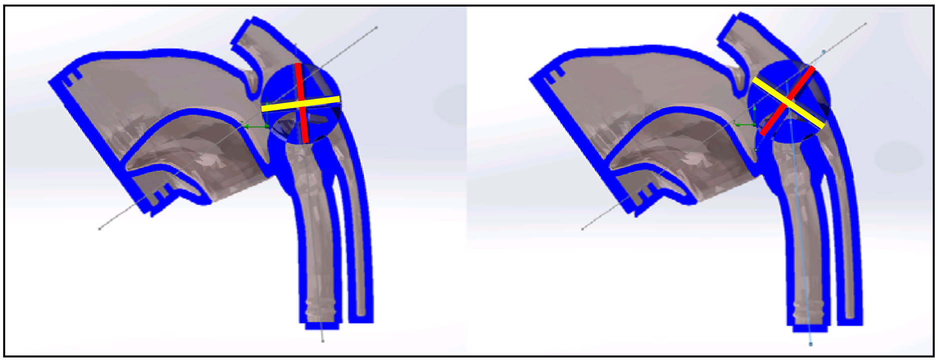


Figure 72. Results of the analysis of the sphere with 3-mm holes in P2 (left: initial position [0 degree], right: 60 degrees)

(c) Spheres with holes located in P3

An analysis of obstruction in P3 showed that airflow was observed in some orientations. Orientations with observed airflow included 9 of 18 points (50%) for 2-mm holes and 3-mm holes and 11 points (61%) for 4-mm holes. In addition, suction pressure varied with the hole size or sphere orientation, even in the presence of airflow.

Therefore, suction pressure was calculated as a measure for comparison of difficulty in suction to determine the magnification ratio relative to the suction pressure in the open state of 31.09 Pa.[68]

The results indicated that suction pressure was the lowest for 4-mm holes and less than 10-fold of the suction pressure in the open state in six orientations. Suction pressure for 3-mm holes was higher than that for 4-mm holes and not more than 20-fold of the suction pressure in the open state in six orientations. For 2-mm holes, suction pressure was not less than 50-fold of the suction pressure in the open state in all nine orientations with observed airflow (Figure 73).

[68] At the suction pressure of 3,109 Pa, suction is difficult, because suction of the same volume is impossible unless there is 100-fold of the suction pressure in the open state. A higher magnification ratio indicates more difficult suction and a higher risk of choking.

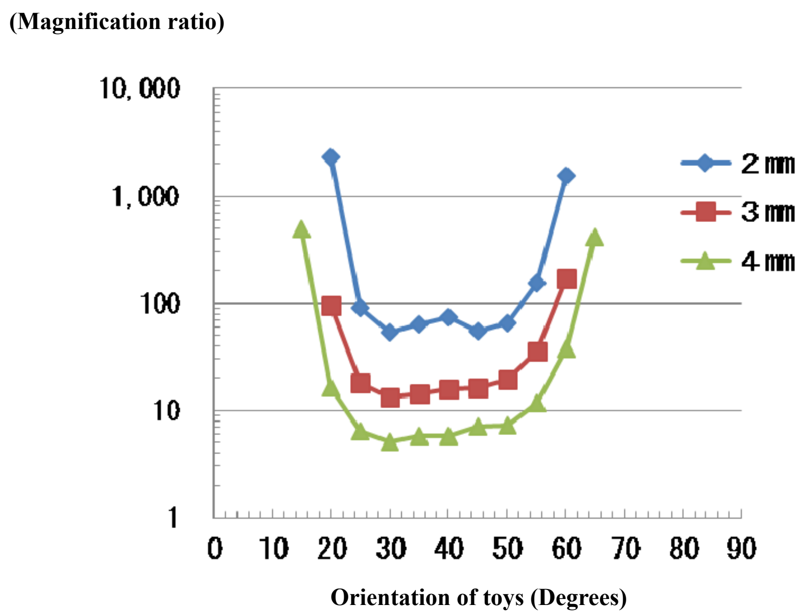


Figure 73. Suction pressure in P3 (magnification ratio relative to the open state)

These results indicated that respiration tended to be easier with an increase in hole size. It is probable that making as large holes as possible increases the potential for avoidance of complete obstruction of the pharyngeal cavity.

Next, a pathline of the analysis results in the orientation with the lowest suction pressure for each shape is provided (Figure 74). The results show that air flows through multiple holes that get crossed in the center, but not in a linear fashion. They indicate that making holes in one direction is less effective and making holes in multiple directions that get connected in the center to form multiple passages is required to avoid pharyngeal obstruction-type asphyxiation, because the pharynx is not a cylindrical tube standing upright.

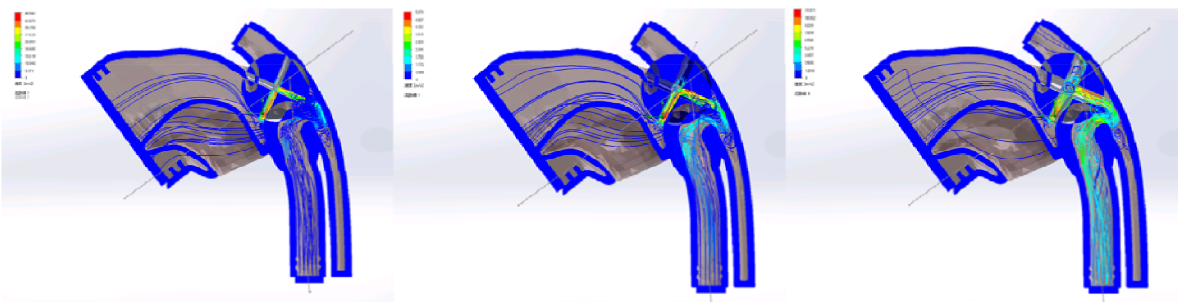


Figure 74. Pathline diagrams in the orientation with the lowest suction pressure in P3

(Left: 2-mm hole, mid: 3-mm hole, right: 4-mm hole)

In addition, the regular dodecahedron was characterized by inflow of all air from the nasal cavity without any inflow from the mouth. For example, the results of the analysis at 155 degrees with the lowest suction pressure are provided in a pathline diagram (Figure 75). Even if suction is blocked in a structural narrowed area between the soft palate and tongue, which is called the faucial isthmus, airway from the nasal cavity may be maintained at the back of the pharyngeal cavity with a relatively large space in a regular dodecahedron.

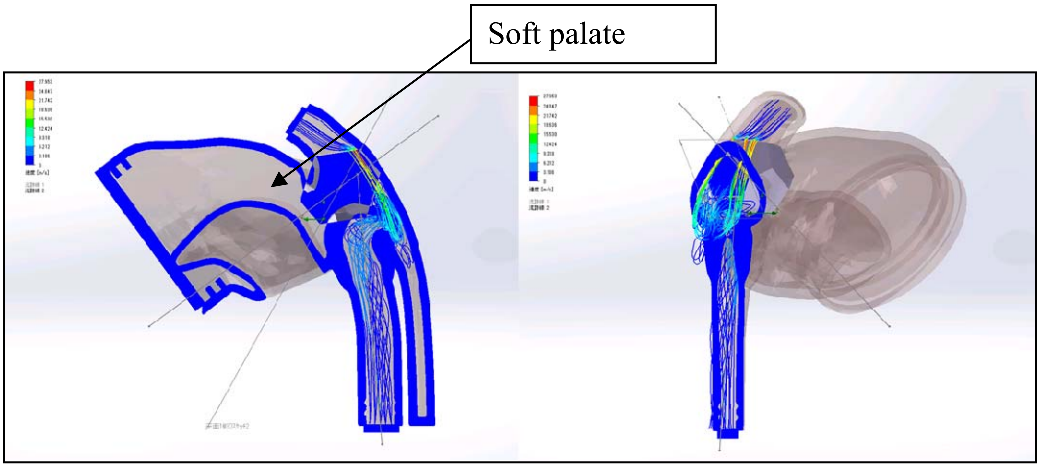


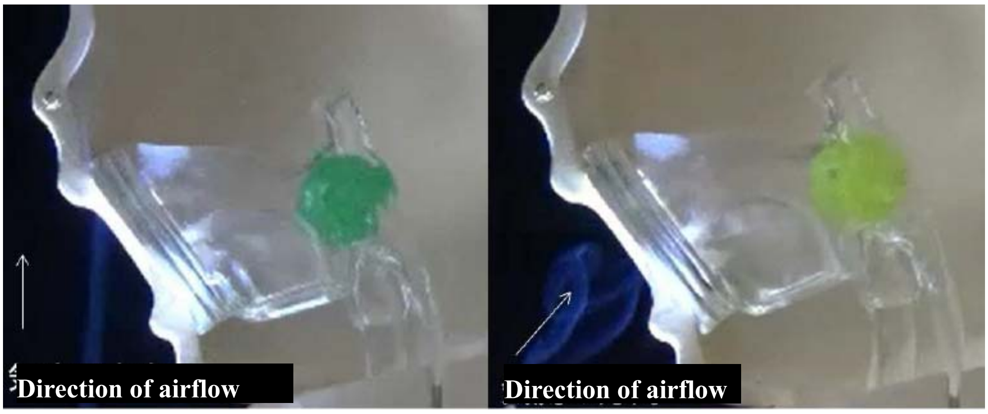
Figure 75. Pathline diagram in the orientation with the lowest suction pressure in the regular dodecahedron
(Left: cross section from the right side, right: coronal cross section)

5.3.5 Suction Experiment on Balls with Holes Using a Phantom Model

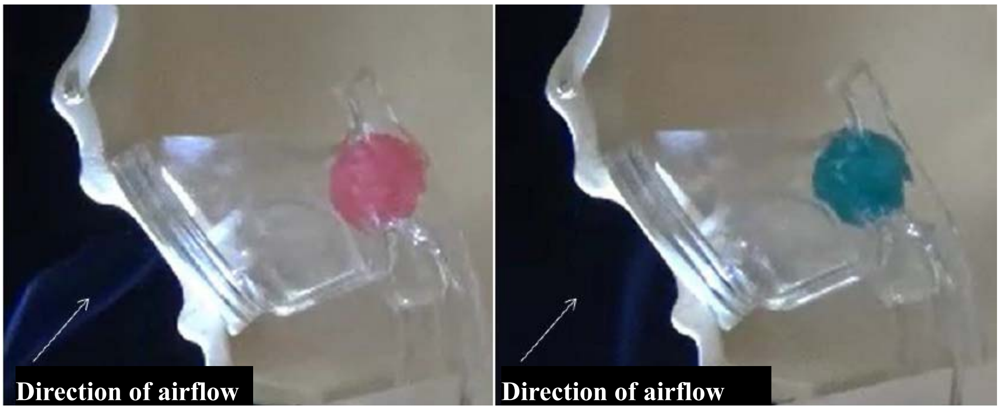
As with toy models used for airflow simulation, bouncing balls 20 mm in diameter with 2-mm, 3-mm, and 4-mm holes were actually created and were allowed to obstruct the pharynx of a phantom model[69] to perform an experiment for the presence of airflow.
To directly visualize airflow, incense smoke was used. Suction was performed from the side of an Ambu bag[70] of the phantom model and videos were shot to determine whether incense smoke brought close to the mouth was inhaled. The videos showed that no smoke was inhaled in the absence of holes, a small amount of smoke was inhaled in the presence of 2-mm holes, and smoke flowed in the direction of the mouth in the presence of 3-mm and 4-mm holes (Picture 7 and Picture 8). In addition, measurement

[69] A human body model reproducing the human body or body organs.
[70] A bag for medical use to deliver air (oxygen) through the mouth and nose in an emergency and other situations. An Ambu bag for children was used as the lung of the phantom model considering the expiratory volume of infants.

of wind speed at the tip of the mouth under the conditions found that wind speed was increased with the size of the holes (Table 15).



Picture 7. Images from the phantom experiment (left: ball without holes, right: ball with 2-mm holes)



Picture 8. Images from the phantom experiment (Left: ball with 3-mm holes, right: ball with 4-mm holes)

Table 15. Results of measurement of wind speed at the tip of the mouth

State of holes	Wind speed
Open	0.35 m/s
4 mm	0.24 m/s
3 mm	0.20 m/s
2 mm	0.13 m/s
Obstructed	0.02 m/s

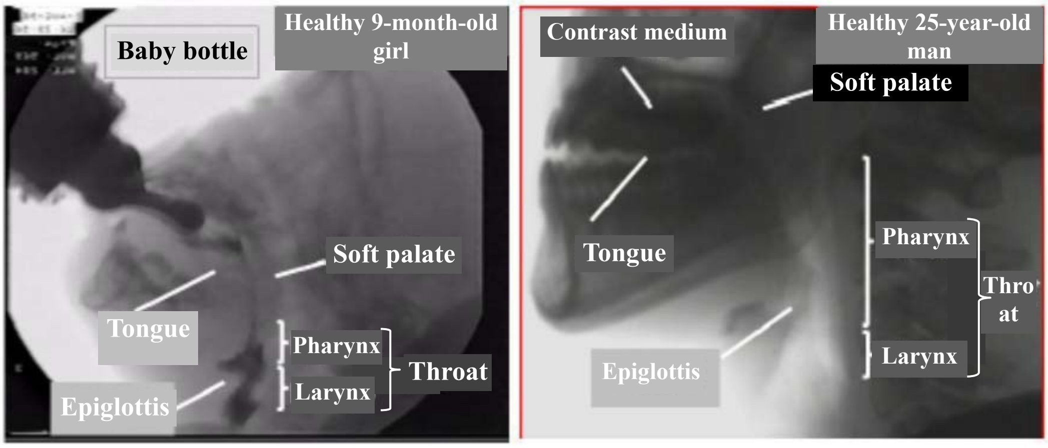
6. Discussion

Discussion was done in light of the results from questionnaire surveys and computer simulations.

6.1 Characteristics of Infants and Aspiration Accidents

6.1.1 Why do Objects Enter the Throat (Pharynx and Larynx) through the Mouth?

When a solid enters the mouth, adults first chew it to fluidize it. At the age of approximately six months to one year and six months, when the formation of four upper and lower front tooth is completed, infants cannot adequately chew food, because they have an incomplete set of teeth.
Swallowing movement is different between adults and infants. For example, the comparison of the movements during swallowing of liquid in a 9-month-old child (a healthy 9-month-old girl) and an adult (a healthy 25-year-old man) with available videofluoroscopic images of swallowing shows that the adult holds liquid in the mouth and then swallows it at a gulp, whereas the 9-month-old child holds liquid in the pharynx but not in the mouth and swallows it after a certain volume is held in the pharynx (Picture 9).



Picture 9. Videofluoroscopic images of swallowing (left: 9-month-old child[71], right: adult)

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[71] Hiroyuki Haishima, et al. "Observation of swallowing movement in a nine-month-old child with an X-ray TV – comparison of swallowing between infants and adults" Japanese Journal of Dysphasia Rehabilitation, Vol.1 p33-44, 1997 (in Japanese)

Thus, infants have a short distance between the mouth and throat (pharynx and larynx) facilitating the entry of objects into the throat through the mouth due to a difference in swallowing movement and infants' anatomical characteristics of a flat and narrow pharyngeal space and the high position of the larynx (the larynx close to the nasal cavity). In addition, infants secrete much saliva, increasing the likelihood that objects put into the mouth may enter the pharynx without frictional resistance.

6.1.2 Why does an Object Lodge in (Obstruct) the Throat (Pharynx and Larynx)?

Voluntary movements such as ingesting and expelling something take place in the mouth, whereas involuntary movements take place in the pharynx and larynx, including swallowing, vomiting, and choking.
In infants, the size of the pharynx is smaller than the maximal mouth opening. Thus, objects entering the mouth are likely to be lodged in the throat without passing through the throat. In addition, infants have less well-developed muscles of the mouth and pharynx than adults and have a weak strength to ingest and expel something. Thus, they have difficulty in removing (swallowing and vomiting) an object on their own once it gets lodged in the throat.

6.2 Characteristics of Toys Likely to be Aspirated (Discussion Based on the Results from the Questionnaire Survey among Parents/Guardians)

The results from the questionnaire survey among parents/guardians found that aspiration accidents caused by toys frequently occurred in infants younger than three years, especially those aged between six months and one year and 6 months. This is probably related to the process of children's growth. Children are perceived to start weaning around the age of five to six months and complete it around the age of one year to one year and six months[72], which coincides with the time when they get more motivated to touch something on their own with development of their ability to move. In addition, infants have the characteristic that they "put anything in their mouth."
For the type of frequently aspirated toys, "marbles" was the most common response, followed by "bead-based toys" and "small balls." For the size, "6 to 10 mm" was the most common response, followed by "11 to 20 mm" and "0 to 5 mm." For the shape, "objects of the same size when viewed from any plane (such as spheres and cubes)" was the most common response, followed by "flat objects."

[72] Ministry of Health, Labour and Welfare "Breastfeeding and Weaning Guide" (March 14, 2007)

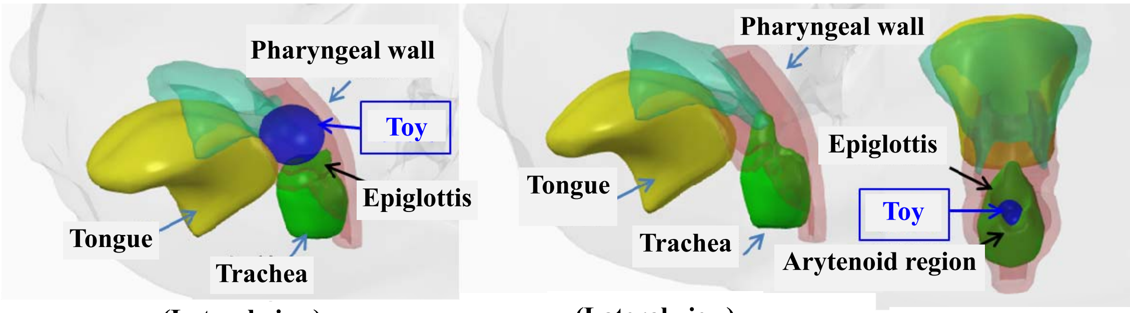
For the material, hard materials such as plastic were commonly used, probably related to the fact that most materials of commercially available toys are such materials.
For the color, the most common colors were blue and red. This may be related to the preference of infants for fundamental hues such as red, blue, and yellow[73] and the wide commercial availability of toys of these colors.
Finally, the results of the questionnaire survey among parents/guardians suggested that the products that were intended for children younger than three years, but were not more than approximately 30 mm in size[74] and did not appear to have their safety assured[75] were commercially available (Figure 36). It is thus possible that some toy-related enterprises design and manufacture products or specify and indicate the intended age without regard to standards for the safety of toys.

6.3 Discussion of the Computer Simulation

6.3.1 Classification and Characteristics of Choking by Area Obstructed by Toys

Choking can be classified into the pharyngeal obstruction-type and laryngeal obstruction-type according to the area in which foreign substances such as toys are lodged. Pharyngeal obstruction-type choking refers to the obstruction of the pharynx by a toy to interfere with breathing (Figure 76(a)). Laryngeal obstruction-type choking refers to the obstruction of the larynx by a toy that is lodged above the glottis (Figure 76(b)).

[73] Toshio Mori, Masumi Saito, Kyoko Kajiura. "Color features preferred by infants" (Major in Home and Life Sciences, Department of Home and Life Sciences, Faculty of Home Economics, Gifu Women's University, September 15, 2010).
[74] Values indicated considering safety based on ST Standard (See Section 3.3.3 (1)).
[75] Whether these toys bore the ST Mark is unknown.



(Lateral view) **(Lateral view)** **(Dorsal view)**

(a) Pharyngeal obstruction-type choking

Shape: Sphere Diameter: 15 mm Hardness: Rigid Friction coefficient: 0.05 Restitution coefficient: 0.03

(b) Laryngeal obstruction-type choking

Shape: Sphere Diameter: 6 mm Hardness: Rigid Friction coefficient: 0.05 Restitution coefficient: 1.0

Figure 76. Pharyngeal obstruction-type choking and laryngeal obstruction-type choking

The results of the simulation analysis found that pharyngeal obstruction-type choking commonly presented with not only obstruction of the pharyngeal cavity by a toy but also obstruction of the laryngeal aperture with downward pressure on the epiglottis from above by the toy. The pharyngeal cavity and laryngeal cavity are simultaneously blocked, resulting in short time in respiratory arrest. It is highly probable that there is a very high risk of asphyxiation.

In laryngeal obstruction-type choking, a toy is present in the larynx but the epiglottis does not cover the laryngeal aperture, which remains open. The laryngeal cavity is not a simple tube or cylinder in shape, but has folds with its opening being not vertically oriented. In addition, it is highly probable that it is difficult to expel a toy entering the larynx with cough reflex because infants have a poor strength to expel foreign matter. However, because the laryngeal aperture and pharynx are open, it is probable that breathing is possible to some extent if there is space left in the larynx, making the degree of seriousness lower than that in pharyngeal obstruction-type choking, although the risk of asphyxiation remains high.

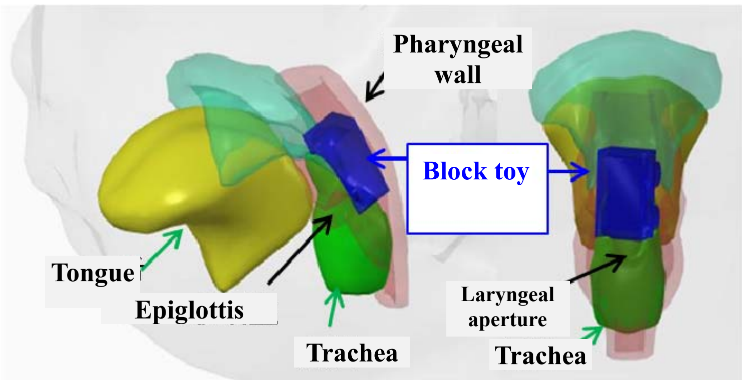
6.3.2 Shape of Toys Showing High Risk of Choking

The sphere showed “high” and “intermediate” risk of choking in 9 and 1, respectively, of a total of 10 sessions of simulation performed under multiple conditions, indicating that the sphere showed high risk of choking under the conditions analyzed. In the case of the sphere, relatively large objects caused pharyngeal obstruction-type choking and small objects entered the larynx to cause laryngeal obstruction-type choking.

Because infants have much saliva in their mouth, toys are likely to slip into the pharynx. In addition, because the tongue is horizontal in the mouth (tongue body) and represents an almost vertical slope (tongue root) on the pharynx, spherical toys are likely to drop down into the pharynx. In addition, the shape of the pharyngeal cavity is crescentic in shape during breathing. When food coming in from the mouth enters the pharynx during swallowing, the pharyngeal cavity takes a sphere-like shape because of a dimple made in the center of the tongue root. After food enters the pharynx, the cavity is closed, squeezed anteriorly and laterally. Thus, the sphere is a shape that fits into the pharyngeal cavity and is therefore likely to lodge in the pharynx and block the pharyngeal cavity once entering the pharynx. Even when an attempt is made to expel a spherical object into the mouth, the object is hampered by the soft palate on the upper side and by bulges located on the lateral pharyngeal walls (palatine tonsils) on the sides and therefore remains in the pharynx for a long time, probably leading to serious disease.

The results from the simulation analysis showed that the rugby ball shape and peanut shape, as well as spherical objects such as balls, caused pharyngeal obstruction-type choking when they were large in size and laryngeal obstruction-type choking when they were small in size.

On the other hand, the cuboid, cube, or block toy did not cause complete obstruction of the pharyngeal cavity, because some space was left in the pharyngeal cavity; however, they blocked the laryngeal aperture by applying downward pressure to the epiglottis from above (Figure 77).



Shape: Block toy
Hardness: Rigid
Friction coefficient: 0.05
Restitution coefficient: 0.03

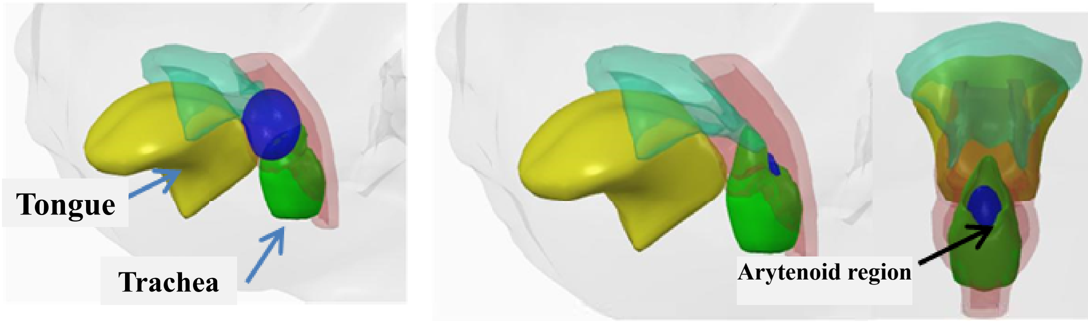
Figure 77. Example of pressure on the epiglottis exerted by the toy block

Next, the airway simulation and experiment on airflow using the phantom model determined whether modifications to the shape of toys could ensure an open airway. It is

highly probable that objects having a shape closer to the sphere are associated with greater difficulty in maintaining an open airway and higher risk of choking.
If holes are made in the sphere to prevent asphyxiation, holes in a single direction are not enough because the pharynx is not a cylindrical tube standing upright. It is somewhat likely that holes in multiple directions getting connected at the center position help to prevent asphyxiation, depending on the position in which the toy lodges. In this case, it is probable that larger holes are associated with higher likelihood of freedom from obstruction and lower suction pressure, thereby facilitating breathing.

6.3.3 Size of Toys Showing High Risk of Choking

The space of the pharynx is larger than that of the larynx. Therefore, it is highly probable that toys obstructing the pharynx are larger in size than toys obstructing the larynx.
The results of the simulation analysis showed that the spheres having a diameter ranging from 15 to 20 mm obstructed the pharyngeal cavity. For a smaller sphere 10 mm in diameter, breathing was possible under certain conditions. For the sphere 6 mm in diameter, it is probable that breathing is difficult due to obstruction of the laryngeal cavity, although some space is left in the pharynx.
For the hemisphere, a diameter of 20 mm showed “high” risk of choking, because the pharyngeal cavity was almost completely obstructed and downward pressure on the epiglottis caused obstruction of the laryngeal aperture, although changes in orientation made some space in the laryngeal aperture in some cases. For a diameter of 15 mm, it is probable that breathing is possible because larger space was left in the pharyngeal cavity, less pressure was exerted on the larynx, and the laryngeal aperture was kept open.
For the rugby ball shape, a size with a minor diameter of 14 mm caused the laryngeal cavity to be almost completely obstructed and the laryngeal aperture to be semi-obstructed by the epiglottis on which downward pressure was exerted (Figure 78(a)). The peanut shape, cuboid, cube, or block toy lodged in the pharynx with some space left in the pharyngeal cavity, but applied pressure to the epiglottis to cause obstruction of the laryngeal aperture when they had a major diameter or diagonal line length of at least 15 mm.



(a) Pharyngeal obstruction

(b) Laryngeal obstruction

Shape: Rugby ball shape
Minor diameter: 14 mm
Hardness: Rigid
Friction coefficient: 0.05
Restitution coefficient: 0.03

Shape: Rugby ball shape
Minor diameter: 7 mm Hardness: Rigid
Friction coefficient: 0.1 for the tongue/palate, 0.2 for the positions below the pharynx
Restitution coefficient: 0.03 for the tongue/palate, 0.8 for below the pharynx

Figure 78. Pharyngeal and laryngeal obstructions

The results showed that all the shapes subjected to the simulation, except the block shape and marble-shaped toy, posed a high risk of pharyngeal obstruction-type choking, which refers to complete or almost complete obstruction of the pharyngeal cavity. In particular, the spherical objects having a diameter of at least 15 mm completely obstructed the pharyngeal cavity, accompanied by obstruction of the laryngeal aperture.
On the other hand, the sphere 6 mm in diameter, peanut shape, and block toy were found to pose a high risk of laryngeal obstruction-type choking, which refers to complete or almost complete obstruction caused by the obstruction of the laryngeal aperture by toys rather than pressure on the epiglottis from above.
Therefore, it is probably that even toys of a size that cannot obstruct the pharynx pose a high risk of choking by obstructing the laryngeal cavity.

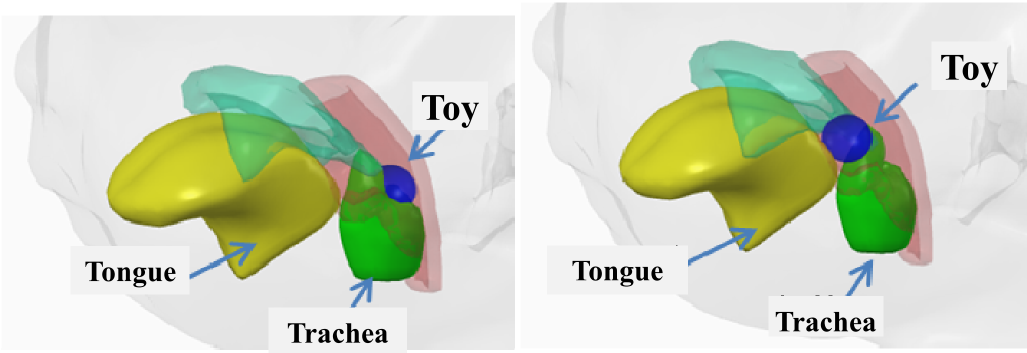
6.3.4 Coefficients of Friction and Restitution of Toys

The coefficient of friction is a coefficient that describes the slipperiness of a toy on the mucosal surface of the tongue or pharynx. Coefficients of friction of toys on mucosal surfaces in infants have not been known to be investigated or reported by other institutions and are also difficult to actually measure. Since infants secrete much saliva, it is probable that coefficients of friction are low, which means that slipperiness is high. Therefore, “notably slippery conditions” and “slippery conditions” were used. More specifically, with a standard coefficient of friction of 0.05 in the tongue, palate, and the other positions below the pharynx, the following two simulations were performed: one with a coefficient of friction of 0.1 of toys located in the tongue or palate under the assumption of “slippery conditions” and the other with a coefficient of friction of 0.2 of toys located below the pharynx under the assumption of “notably slippery conditions.”

The coefficient of restitution is a coefficient that describes how much a toy bounces back from a living body. As with a coefficient of friction, coefficients of restitution have not been known to be investigated or reported by other institutions and were also difficult to actually measure. With reference to values from experiments using the porcine tongue mucosa, the following two simulations were performed: one with a coefficient of restitution of 0.03 in the tongue, palate, and the other located below the pharynx and the other with a coefficient of restitution of 0.03 in the tongue and palate and a coefficient of restitution of 0.8, indicating a greater degree of bounce, below the pharynx.

The results of the above simulation analyses showed that the sphere 10 mm in diameter entered the laryngeal cavity to cause laryngeal obstruction-type choking under conditions of a coefficient of friction of 0.05 and a coefficient of restitution of 1.0 (Figure 79(a)), but stayed in the epiglottis valley[76] and showed only “intermediate” risk of choking under conditions of a higher coefficient of friction of (0.1 for the tongue and palate and 0.2 for the positions below the pharynx) and a lower coefficient of restitution (0.03 for the tongue and palate and 0.8 for the positions below the pharynx) (Figure 79(b)).

[76] The boundary between the tongue root and epiglottis and named after its form of V-shaped valley.



(a) Toy located in the laryngeal cavity

(b) Toy staying in the epiglottis valley

Shape: Sphere Minor diameter: 10 mm
Hardness: Rigid
Friction coefficient: 0.05
Restitution coefficient: 1.0

Shape: Sphere Minor diameter: 10 mm Hardness: Rigid
Friction coefficient: 0.1 for the tongue/palate, 0.2 for the positions below the pharynx
Restitution coefficient: 0.03 for the tongue/palate, 0.8 for the positions below the pharynx

Figure 79. Comparisons of different coefficients of friction and coefficients of restitution

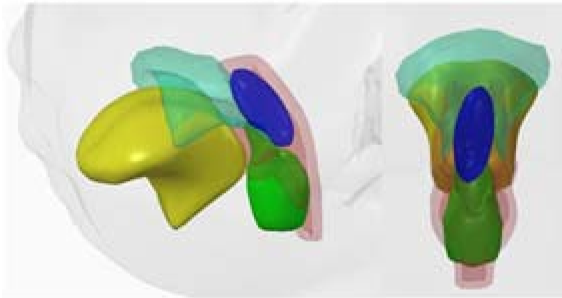
According to the results of this simulation analyses, it is possible that the coefficient of friction or coefficient of restitution of a toy affects the movement of the toy from the pharynx toward the larynx, as well as its slipperiness from the mouth to the pharynx.

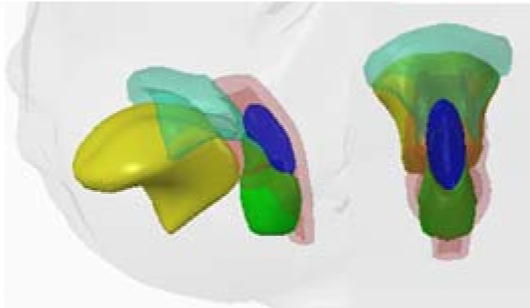
6.3.5 Hardness of Toys

To determine the effects of the hardness of toys, simulations were performed to analyze choking risk at different levels of elasticity. The Young's modulus of elastic bodies was 20 kPa.

The results showed that the movement of toys remained unchanged with no change in choking risk for any of the sphere, peanut shape, and cube subjected to simulation at different levels of elasticity (Figure 80(a) and (b)).

This means that the results of the simulation analyses cannot identify the possibility of differences in choking risk among levels of elasticity of toys.





(a) Peanut shape (rigid body) (b) Peanut shape (elastic body)

Minor diameter: 10 mm Major diameter: 23 mm Hardness: Rigid Friction coefficient: 0.1 for the tongue/palate 0.2 for the positions below the pharynx Restitution coefficient: 0.03 for the tongue/palate 0.8 for the positions below the pharynx	Minor diameter: 10 mm Major diameter: 23 mm Hardness: Elastic (Young's modulus of 20 kPa) Friction coefficient: 0.1 for the tongue/palate 0.2 for the positions below the pharynx Restitution coefficient: 0.03 for the tongue/palate 0.8 for the positions below the pharynx

Figure 80. Comparison of different levels of hardness of the peanut shape

6.3.6 Guide of Toys Causing Choking (Summary)

The results of the simulation analyses under different conditions of the shape, size, coefficient of friction, coefficient of restitution, and elasticity of toys can be summarized as follows:

All the shapes subjected to simulation, that is, the sphere, hemisphere, ellipse, cuboid, cube, and block toy, completely or almost completely obstructed the pharyngeal or laryngeal cavity and were found to pose a high risk of choking. For the size of toys, large objects caused pharyngeal obstruction-type choking and even small objects caused laryngeal obstruction-type choking, depending on the shape. For the sphere, for example, a diameter of 6 to 20 mm caused choking.

Although the result of the simulation analyses in a nine-month-old child cannot be generalized to children at other ages in months because of potential changes in depth or width of the mouth or pharynx with growth, it is highly probable that the size of toys affects choking risk.

6.3.7 Results of a Simulation Analysis on the Case Filed

For the pacifier-shaped toy described in the case filed (Figure 81), an airway obstruction simulation was performed. It should be noted that the simulation is not a reproductive experiment of the accident.

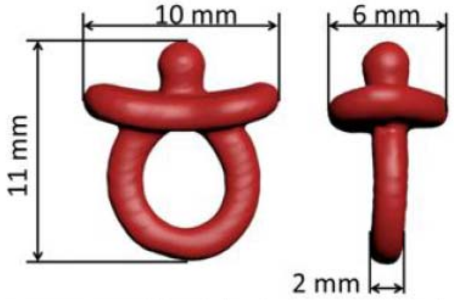
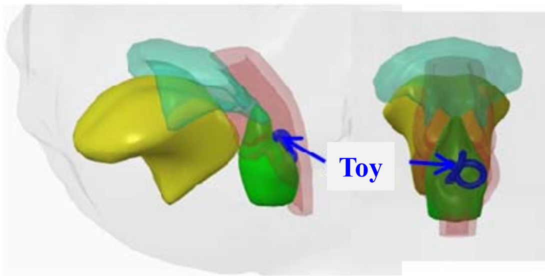


Figure 81. Shape model of the pacifier-shaped mode

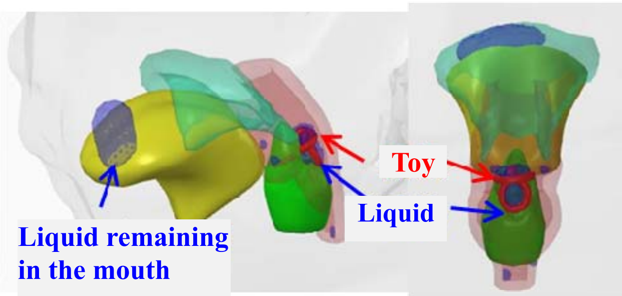
First, simulations were performed under multiple conditions, assuming aspiration of the pacifier-shaped toy alone. The results showed that, regardless of the orientation of the relevant toy, some models stayed in the hypopharynx or entered the larynx, but could not be considered to cause pharyngeal or laryngeal obstruction. It is probable that respiratory arrest is not caused in a short time (Figure 82(a)).

Next, because the statement “While eating baby food, a 9-month-old boy suddenly turned pale and gradually got exhausted” was included in the filing, ingestion of the relevant toy along with viscous liquid was simulated. The results showed that the toy with liquid getting entangled around it stopped in the oropharynx (epiglottis valley). In this case, because the epiglottis was in rest position, the laryngeal aperture was open, and the pharyngeal cavity and the laryngeal cavity were both kept open, breathing was possible and choking risk was not high.

As described earlier, when an object is present in the pharynx, an attempt is made to expel it into the mouth or swallowing is repeated to ingest it. Both movements are reflex, but not voluntary. Because infants have a weak strength to expel something, the process from the condition after the first swallowing to the second swallowing movement was simulated, assuming that swallowing was repeated. The results showed that the toy with liquid moved to the laryngeal aperture. The disc part of the pacifier got into contact with the reverse side of the epiglottis and the ring part of the pacifier with liquid was located in the larynx. The hollow part of the ring was filled with liquid and the entire toy almost completely blocked the laryngeal aperture, posing a risk of laryngeal obstruction-type choking (Figure 82(b)).



(a) After swallowing the toy alone



(b) After the first swallowing of a mixture of the toy and liquid followed by the second swallowing

Hardness: Rigid
Friction coefficient: 0.1 for the tongue/palate, 0.2 for the positions below the pharynx
Restitution coefficient: 0.03 for the tongue/palate, 0.8 for the positions below the pharynx

Hardness: Rigid
Friction coefficient: 0.1 for the tongue/palate, 0.2 for the positions below the pharynx
Restitution coefficient: 0.03 for the tongue/palate, 0.8 for the positions below the pharynx
Viscosity of liquid: 100 mPa･s (equivalent to condensed milk)

Figure 82. Choking caused by the pacifier-shaped toy

When infants have an adequately strong power to exhale, it is somewhat likely that they can cough to dissipate and remove the liquid. On the other hand, because infants have much saliva, which is more viscous than water, saliva might have gotten entangled in the toy when it poured into the pharynx. Because the toy was not easy to remove from the larynx or hypopharynx with the infant's power to expel something, it is possible that hypoxia progressed with time.
The results of the simulation analyses suggest that toys of sizes and shapes that are unlikely to independently cause pharyngeal or laryngeal obstruction may cause choking with viscous liquid, etc. when entering the mouth and lodging in the pharynx or larynx.

6.4 Current Situation of Sharing of Information on Accidents

The questionnaire survey among parents/guardians and data on emergency transportation showed that a certain number of swallowing accidents due to toys occurred even when they might not lead to airway obstruction. On the other hand, the results of the questionnaire survey among toy-related enterprises showed that only a few toy-related enterprises obtained information on the occurrence of swallowing accidents.
For accident information data banks, only two cases of airway obstruction accidents due to toys have been registered over a period of eight years, highlighting that information on aspiration or airway obstruction accidents occurring at home is not shared among

concerned parties, including administrative bodies.

6.5 Awareness of Parents/Guardians in Buying Toys

“Interest of children” was the most common response to the question about what parents/guardians placed importance on when buying toys, provided by 73% of parents/guardians, followed by “safety” (64%) and “price” (37%). Older parents/guardians tended to place greater importance on safety when buying toys.

Also, in determining the safety of toys, parents/guardians tended to place greater importance on the size or shape of toys rather than marks or precautionary statements for safety indicated on products, regardless of age.

In response to the question about the awareness of marks for safety, such as the ST Mark, approximately 50% of parents/guardians had seen such marks but did not know their meaning. On the other hand, parents/guardians who had seen the ST Mark and also knew its meaning were asked whether the presence or absence of the ST Mark contributed to their decision of whether to buy the toy. The results showed that approximately 75% of parents/guardians responded “Yes” or “Maybe yes.” It is therefore probable that the ST Mark played a certain role as a determinant to select and buy safe toys in parents/guardians who had an understanding of the meaning of the ST Mark.

Approximately 80% of parents/guardians responded that they “checked” or “maybe checked” the intended age for toys. Among them, at least 60% of parents/guardians responded that they “bought” or “maybe bought” toys even when they had children at home who were under the intended age for the toys. The reasons for buying such toys included high priority given to raising the level of children or interest of children. It is possible that the intended age may not be understood by parents/guardians even if it has been established considering children’s development or safety.

6.6 Actions in Case of Swallowing Accidents

All respondents to the questionnaire survey (2,164 respondents) were asked about possible actions to be taken in case that their children experienced accidental ingestion or aspiration. The results showed that the most commonly given responses included “patting the child’s back,” “putting the finger into the child’s mouth,” and “turning the child upside down,” consistent with the actions taken by individuals who encountered actual swallowing accidents.

The results found that the “back blow maneuver” or “Heimlich (abdominal thrust) maneuver,” which are recommended actions to be taken in case of airway obstruction in life-saving training or maternal and child health handbooks, were not pervasive in home settings.

7. Conclusion

The questionnaire survey among parents/guardians to determine what age groups of children experience aspiration and what types of toys were aspirated demonstrated that such accidents frequently occurred in infants younger than three years, especially those aged between six months and one year and six months. In addition, “marbles” was the most common type of toys, followed by “bead-based toys” and “small balls.” For the size, “6 to 10 mm” was the most common, followed by “11 to 20 mm” and “0 to 5 mm.” For the shape, “objects of the same size when viewed from any plane (such as spheres and cubes)” was the most common, followed by “flat objects.”

It is probable that the behavioral characteristic of “putting anything in the mouth,” observed especially in infants, also contributes to aspiration of toys. In addition, physical characteristics of infants, such as the size of the pharynx smaller than the maximal mouth opening, the mouth close to the throat, much saliva, and inadequate ability to expel (swallow/vomit) something that lodges in the throat on their own, also may prompt an aspirated toy to lodge in the throat (pharynx/larynx) to cause airway obstruction.

To elucidate the mechanism of such airway obstruction due to toys, as well as to gain insights into the size or shape of toys that caused airway obstruction, the airway obstruction simulation and airflow simulation analyses were performed using the CT images and videofluoroscopic images of swallowing from a nine-month-old child.

These analyses showed that all the shapes, that is, the sphere, hemisphere, ellipse, cuboid, cube, and block toy, caused complete airway obstruction and posed a high risk of choking. The rugby ball shape and peanut shape, as well as the sphere, caused pharyngeal obstruction-type choking when they were large in size and laryngeal obstruction-type choking when they were small in size. On the other hand, the cuboid, cube, and block toy did not cause complete obstruction of the pharyngeal cavity, because some space was left in the pharyngeal cavity; however, they blocked the laryngeal aperture by applying downward pressure to the epiglottis from above.

In addition, these simulations also suggested that toys that were unlikely to cause obstruction of airway (pharynx/larynx) based on their size or shape may stay in the pharynx or larynx together with liquid to cause airway obstruction and therefore asphyxiation when they entered the pharynx or larynx, mixed with viscous liquid.

The questionnaire survey among parents/guardians suggested that some toy-related enterprises may design and manufacture toys or specify and indicate the intended age without regard to standards for the safety of toys, even though toys familiar to infants may obstruct the airway to cause asphyxiation. It is also possible that parents/guardians do not fully understand that intended ages are determined with regard to the development of children and safety aspects.

It was also found that the “back blow maneuver” and “Heimlich (abdominal thrust) maneuver,” actions to be taken in case of accidents, were not pervasive in home settings, although they are recommended in maternal and child health handbooks or local life-saving training sessions are held.

In addition, it was found that a certain number of accidents of aspiration of toys occurred, while information on accidents was not shared among toy-related enterprises and administrative bodies.

8. Measures to Prevent Recurrence

The behavioral characteristic of "putting anything in the mouth" is observed in infants. In addition, physical characteristics, such as the size of the pharynx smaller than the maximal mouth opening, the mouth close to the throat, much saliva, and inadequate ability to expel (swallow/vomit) something that lodges in the throat on their own, are also observed.

As described in Section 7 "Conclusion," it is not unlikely that toys familiar to children cause aspiration and therefore a serious accident of choking in light of these behavioral and physical characteristics observed in infants.

The Investigation Commission feels that it is important and the role of administrative bodies, toy-related enterprises, and parents/guardians to create an environment in which children can play with toys safely and happily, because playing with toys is an important experience for children and small toys also have roles in contributing to the development of hands of children and satisfying their curiosity.

It is important for all parties involved with children to first understand characteristics of infants and then recognize characteristics of toys potentially causing aspiration or choking and risks of accidents.

This report described characteristics of infants and also showed that the airway obstructions simulation performed based on the results of the questionnaire surveys provided insights into the shape or size of toys that are considered to pose a high risk of choking and also demonstrated that even toys with a low risk of choking might pose an increased risk of choking when mixed with viscous liquid, etc.

Based on these investigation results, measures expected to be effective in preventing of recurrence of accidents are summarized below.

8.1 Measures in Design, Manufacture, and Sales

8.1.1 Awareness of the Size and Shape that Possibly Cause Airway Obstruction

The questionnaire survey among parents/guardians showed that "marbles" were the type of toy with the highest incident of aspiration accidents, followed by "bead-based toys" and "small balls." For the size, "6 to 10 mm" was the most common, followed by "11 to 20 mm" and "0 to 5 mm." For the shape, "objects of the same size when viewed from any plane (such as spheres and cubes)" was the most common response, followed by

"flat objects."
The airway obstruction simulation analyses in a nine-month-old child to verify how these toys lead to airway obstruction showed that the shapes of the sphere, hemisphere, ellipse, cuboid, and cube completely obstructed the airway to cause choking. The rugby ball shape and peanut shape, as well as the sphere, caused pharyngeal obstruction-type choking when they were large in size and laryngeal obstruction-type choking when they were small in size. On the other hand, the cuboid, cube, and block toy did not cause complete obstruction of the pharyngeal cavity, because some space was left in the pharyngeal cavity; however, they blocked the laryngeal aperture by applying downward pressure to the epiglottis from above.
In the light of behavioral and physical characteristics of infants, toy-related enterprises need to design, manufacture, and sell toys with reference to the results of these investigations of the size or shape of toys.

8.1.2 Determination of Intended Ages considering Safety Aspects

The questionnaire surveys among parents/guardians indicated that approximately 80% of parents/guardians check intended ages when buying toys. It is probable that an intended age indicated on a toy is an important factor for consumers to determine whether to buy the toy.
Therefore, it is necessary that intended ages should be determined and indicated based on standards or international standards for safety of toys, including the ST Standard.
In addition, the surveys showed that toys that are approximately 30 mm or larger in size tend to be aspirated by children under three years (Figure 19). Most such toys were intended for children over three years, but some of them were intended for children under three years. It is possible that toys that do not meet ST Standard, etc.[77] caused accidents (Figure 36).
To prevent the occurrence of these accidents, it is important to design, manufacture, and sell products considering standards or international standards for safety of toys, including the ST Standard.

8.1.3 Further Efforts to Ensure Safety

The Injury Alert presented an accident case in which a two-year-old child aspirated a toy 35 mm in diameter (diameter in the center: 35 mm, tip part of the object which

[77] Whether the relevant toys carried the ST Mark is unknown.

could be divided into two pieces with a hook and loop fastener) and died about several months later. The relevant toy did not carry the ST Mark; however, if product tests had been performed in accordance with ST Standard, the test using the test template for "small parts" (cylinder) would have applied and the relevant toy had the shape and size that conformed to the test. It is thus possible that this accident might have been prevented if the relevant toy had been designed to conform not only to the small parts test, but also to the small balls test as a proactive approach by the toy-related enterprise or if the toy had been subjected to a test with Accidental Ingestion Checker or other tests.[78]

In addition, it is somewhat likely that choking accidents might be prevented by designing toys with the assumption that they may be thrown by children and broken into small pieces, even if such a design is considered unnecessary considering intended ages.

Furthermore, making as large holes as possible in multiple directions may be an effective twist for avoiding airway obstruction and subsequent asphyxiation if a toy enters the throat (pharynx and larynx).

Based on these findings, toy-related enterprises should consider further safety improvement, including twists to test methods and twists to products.

8.1.4 Dissemination of Meanings of Toy Safety Labels

Toy-related enterprises need to widely and accurately communicate the meanings of intended ages and safety labels such as the ST Mark to consumers such as parents/guardians. In buying a toy, consumers should check information contained in its labeling to determine whether their child reaches its intended age and refrain from buying the toy if the child does not reach the intended age.

8.2 Sharing of Accident Risks and Preventive Measures

8.2.1 Awareness of the Risk of Accidents

It is probable that detailed knowledge of administrative bodies, toy-related enterprises, consumers, etc. about behavioral and physical characteristics of infants and

[78] The manufacturer related to the relevant accident case states that, after this accident, the manufacturer makes independent further efforts to ensure safety, including designing products to conform to standards or international standards for safety of toys such as the ST Standard, using Accidental Ingestion Checker concomitantly during product tests, and avoiding shapes that potentially fit entirely in the throat, such as the sphere.

characteristics of toys that potentially cause aspiration or choking might make them aware of the risk of accidents, leading to prevention of accidents. Widespread use of the movie titled “Protection of children from choking accidents” to illustrate these characteristics and the papercraft “Model of the infant’s mouth and throat” to simulate the mouth, pharynx, larynx, and trachea by parties involved is effective in promoting awareness of the risk of accidents and preventing accidents.

8.2.2 Method of Storing Toys

The Injury Alert presented cases in which toys of older children caused choking accidents in younger children such as infants and the results of the questionnaire survey among parents/guardians showed that toys of older children caused many cases of aspiration accidents (Figure 13).

Based on these findings, it is necessary that consumers should check the reach of younger children and make efforts, especially for objects 6 to 20 mm in size which may cause choking, including keeping them out of reach of such children.

8.2.3 Prevention of Serious Disease

In case of choking, cerebral disorder occurs 5 minutes after respiratory arrest and brain death is caused at 15 minutes. Thus, serious disease develops in a short time after occurrence of choking, therefore raising a need for prompt intervention. It is necessary that consumers should learn actions to be taken in case of choking from experts at their local fire departments or local Japan Red Cross Society branches to be able to take appropriate actions (back blow maneuver, chest thrust maneuver, and Heimlich maneuver) immediately.

8.3 Collection and Sharing of Information on Accidents

The current questionnaire surveys indicated that a certain number of aspiration accidents due to toys occurred, whereas only a limited number of toy-related enterprises have obtained information on such accidents.

In addition, several relevant administrative bodies collect information on aspiration accidents due to toys along with other information, but the number of cases of accidents as suggested by the results of the questionnaire surveys is not reached. In addition, such cases do not provide detailed information, including the situations in case of accidents and the size or shape of toys responsible for accidents.

To ensure that administrative bodies, toy-related enterprises, and consumers take specific recurrence preventive measures to prevent recurrence of accidents, it is crucial to collect and accumulate detailed accident information on situations in which aspiration accidents have occurred and types of toys that have caused accidents and share such information among parties involved.

Possible information on accidents include the age of children in months, type, size, shape, and intended age for a toy with which the accident occurred, conformity to standards for safety of toys such as ST Standard, storage of the toy, owner of the toy, and actions taken, as well as medical data in the event that CT images, etc. have been taken in medical institutions. This information can be used by administrative bodies to implement various measures to prevent recurrence, by enterprises to design, manufacture, and sell safer toys, and by parents/guardians and other consumers to make a decision in buying or storing toys.

For these reasons, it is necessary to share information on accidents as shown above among relevant administrative bodies or toy-related enterprises in case of airway obstruction accidents or aspiration accidents. It is therefore important that relevant administrative bodies develop a system for collecting and accumulating information and also that the whole society is aware of the usefulness of such information and enterprises becoming aware of accidents, medical institutions providing treatment, and parents/guardians of infants suffering accidents report such information.

9. Opinions

To prevent recurrence of accidents, it is necessary that all parties involved with children, including administrative bodies, toy-related enterprises, and consumers, have and share an understanding of the risk of accidents. First, it is important for the parties involved to understand the behavioral characteristic of “putting anything in the mouth” observed in infants and physical characteristics, such as the size of the pharynx smaller than the maximal mouth opening, the mouth close to the throat, much saliva, and inadequate ability to expel (swallow/vomit) something that lodges in the throat on their own and it is a possible role of administrative bodies to disseminate these characteristics.

The Investigation Commission took this occasion to produce the movie titled “Protection of children from choking accidents” and papercraft “Model of the infant’s mouth and throat” to provide parties involved with a detailed and clear description of the above-mentioned behavioral characteristic and physical characteristics of infants and the characteristics of toys that potentially cause aspiration or choking. Wide availability of these materials for parties involved may contribute to prevention of airway obstruction accidents due to toys in children.

9.1 Opinions for the Minister of Economy, Trade and Industry

(1) Dissemination of the Risk of Accidents

The Ministry of Economy, Trade and Industry should encourage toy-related enterprises to understand the behavioral characteristics of infants, structure of the mouth or characteristics of swallowing, and characteristics of toys that potentially cause aspiration or choking in order to manufacture or sell safe toys. To that end, the Ministry should continuously and widely disseminate the behavioral or physical characteristics of infants to toy-related enterprises by reference to this report and the Investigation Commission-produced movie titled “Protection of children from choking accidents” and papercraft “Model of the infant’s mouth and throat.”

(2) Design, Manufacture, and Sales of Safe Toys

(a) The Ministry of Economy, Trade and Industry should encourage toy-related enterprises to ensure that intended ages should be determined and indicated based on standards or international standards for safety of toys, including ST Standard. In addition, the Ministry should verify the effectiveness of the encouragement and should consider further measures if adequate effectiveness is not achieved.

(b) The Ministry of Economy, Trade and Industry should make efforts to ensure that safe toys are designed, manufactured, and sold by asking toy-related enterprises to implement the following efforts:

i) For toys intended for children under three years that are in shapes classified as the sphere, such as the sphere, hemisphere, or ellipse, further safety improvement should be considered by making approaches such as using combinations of various test methods, such as a combination of the "small parts" test and the "small balls" test, designing toys with the assumption that they may be broken into small pieces even if such a design is considered unnecessary considering intended ages, and making as large holes as possible in multiple directions for avoiding airway obstruction and subsequent asphyxiation if a toy enters the throat (pharynx and larynx).

ii) The meanings of intended ages and safety labels such as the ST Mark should be communicated to consumers clearly and accurately.

9.2 Opinions for the Director General of the Consumer Affairs Agency

(1) Dissemination of the Risk of Accidents

The Director General of the Consumer Affairs Agency, as a control tower for prevention of accidents in children, should work with the Cabinet Office, Fire and Disaster Management Agency, Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labour and Welfare, and other appropriate organizations to continuously and widely disseminate the risk of accidents to consumers so that consumers can gain a detailed understanding of the behavioral and physical characteristics of infants, characteristics of toys that potentially cause aspiration or choking, or the risk of accidents by reference to the Investigation Commission-produced movie titled "Protection of children from choking accidents" and papercraft "Model of the infant's mouth and throat" and other materials.

(2) Efforts to Disseminate Accident Preventive Measures

The Consumer Affairs Agency should make efforts leading to specific actions of consumers to prevent accidents, including dissemination of the accident preventive measures to consumers:

(a) Since even toys of sizes and shapes that are unlikely to cause choking may cause choking when mixed with viscous liquid, etc., consumers should check whether foreign substances such as toys are present in the mouth before giving children baby food or milk.

(b) Before buying toys, consumers should check the intended age for them and should refrain from buying them for children who do not reach the intended ages. After buying toys, consumers should check the reach of younger children in advance and keep the above-mentioned toys, especially objects 6 to 20 mm in size, out of the reach of younger children.

(3) Collection and Sharing of Information toward Safety Improvement

The Consumer Affairs Agency should ensure that other administrative bodies, toy-related enterprises, and consumers collect and accumulate and widely share among parties involved information including the age of children in months, type, size, shape, and intended age for a toy with which an accident occurred, conformity to standards or international standards for the safety of toys such as ST Standard, store of the toy, owner of the toy, and action taken so that they can gain a detailed understanding of situations in which accidents such as aspiration and choking have occurred and types of toys that have caused accidents and take specific actions required to prevent recurrence of accidents. In addition, it is desirable to collect and accumulate medical images such as CT images to the extent possible.

(4) Dissemination for Preventing Serious Disease

The Consumer Affairs Agency should work with the Fire and Disaster Management Agency to encourage consumers to learn appropriate actions to be taken in case of airway obstruction (back blow maneuver, chest thrust maneuver, and Heimlich maneuver) from experts at their local fire departments or local Japan Red Cross Society branches.

Reference

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1. About this Reference

This reference details the methods for performing airway obstruction simulations and airflow simulations using Swallow Vision® and describes the development of a phantom (human body model), papercraft "model of the infant's mouth and throat," and movie titled as "Protection of children from choking accidents."

2. Airway Obstruction Simulation

Airway obstruction simulations were performed using Swallow Vision® to determine the mechanism by which toys cause airway obstruction accidents and the likelihood of choking among different shapes or sizes of toys.

2.1 Preliminary Study about using Swallow Vision®

Swallow Vision® is a swallowing simulator developed for elucidating the mechanisms of swallowing and aspiration. The simulator has been validated after the modeling of morphologies of the mouth, pharynx, larynx, esophagus, etc. based on CT images for medical use[1] and the modeling of swallowing movement based on videofluoroscopic images of swallowing or four-dimensional CT images.

The airway obstruction simulations required prior confirmation that Swallow Vision® could be used. For this confirmation, simulations were performed using living body models and foreign matter models.

The results showed that a foreign matter model having a frustoconical shape, a height of 23 mm, a major diameter of 21 mm, a minor diameter of 17 mm, and a Young's modulus[2] of 20 kPa obstructed the pharynx (pharyngeal obstruction-type choking, Figure 1b).

A foreign matter model having an elliptical shape, a short diameter of 5.6 mm, a long diameter of 13 mm, and a Young's modulus of 20 kPa entered the esophagus (Figure 1a).

A foreign matter model having a short diameter of 13.5 mm, a long diameter of 32.5

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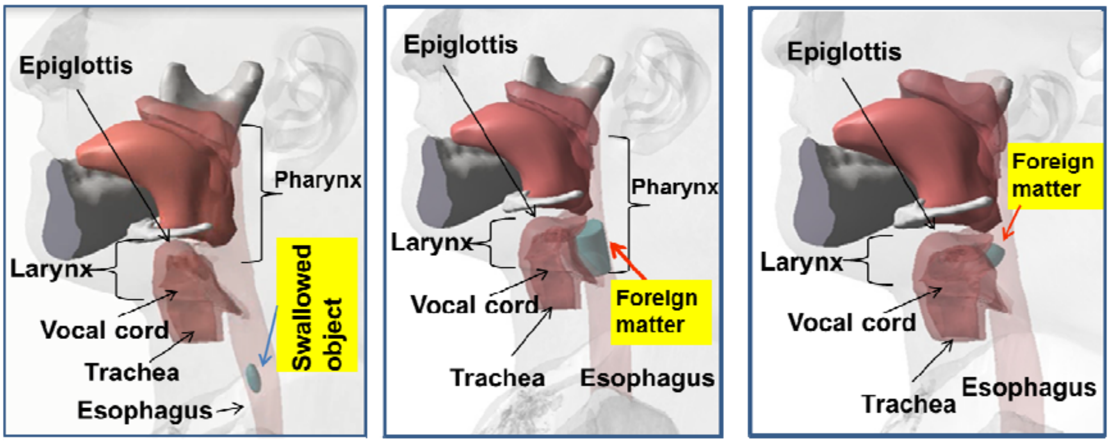
[1] CT images for medical use were used with the approval of Institutional Ethics Review Committee of Musashino Red Cross Hospital.

[2] A ratio of tensile or compressive stress to distortion in the direction of the stress (stretch or shrinkage per unit length) in a solid. A constant specific to a substance. ("Kojien" 6th edition, edited by Izuru Shinmura, Iwanami Shoten, 2008)

mm, and a Young' modulus of 20 kPa obstructed the larynx (larynx obstruction-type choking, Figure 1c).



(a) Swallowing

(b) Pharyngeal obstruction-type choking

(c) Laryngeal obstruction-type choking

Figure 1. Swallowing and choking shown by Swallow Vision®[3]

The above simulations confirmed that Swallow Vision® could be used for elucidating the mechanism of airway obstruction.

2.2 Overview of the Procedure for Performing Airway Obstruction Simulations

Airway obstruction simulations involve numerical models of the living body and toys. Numerical models of the living body were created based on CT images of the head and neck of a 9-month-old boy without swallowing disorder and videofluoroscopic images of swallowing of a 9-month-old girl, because these images were available. Numerical models of toys were created to reflect features of shape, size, hardness, coefficient of friction, coefficient of restitution. Those features were chosen based on results from a questionnaire survey on parents/guardians and reported cases in "Injury Alert,". A total of 48 sessions of airway obstruction simulation, as listed below, were performed using these toy models and the living body model. The results of simulation analysis were finally visualized in a three-dimensional way on a computer.

(a) Sphere: 10 sessions

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[3] The thyroid/cricoid cartilages are not shown and the larynx is semi-transparent with its inside shown.

(b) Hemisphere: 7 sessions

(c) Ellipse[4]: 7 sessions (3 sessions in a rugby ball shape and 4 sessions in a peanut shape)

(d) Cuboid: 2 sessions

(e) Cube: 6 sessions

(f) Block toy: 3 sessions

(g) Marble shape: 5 sessions

(h) Pacifier-shaped toy: 8 sessions

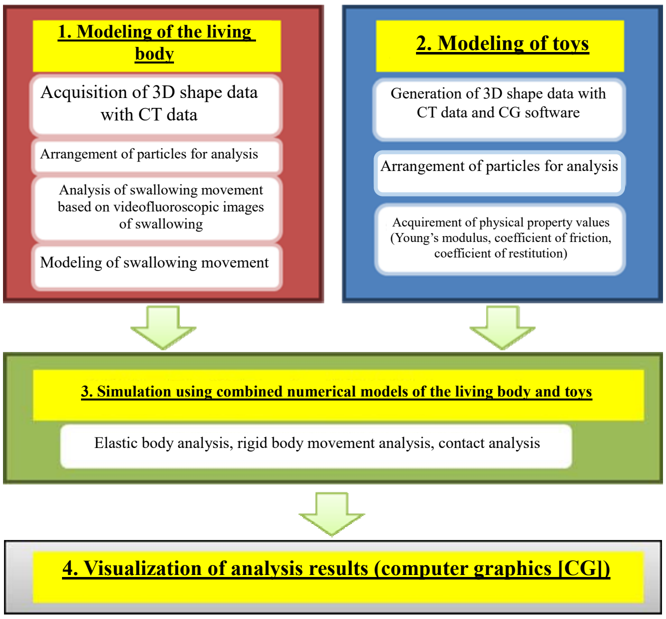


Figure 2. Process of airway obstruction simulation

2.2.1 Creation of Numerical Models of the Living Body

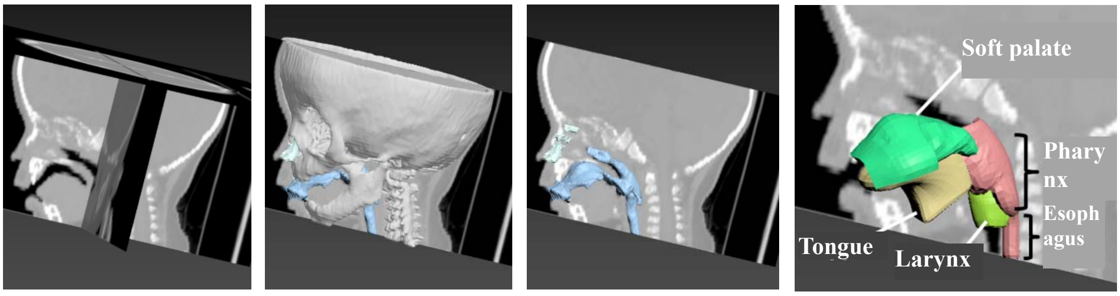
The process of creating numerical models of the living body consists of the following four steps: acquisition of three-dimensional shape data from CT images at rest, arrangement of particles for analysis from three-dimensional shape data, analysis of swallowing movement based on videofluoroscopic images of swallowing, and creation of models of swallowing movement.

(1) Acquisition of Three-dimensional Shape Data from an Infant at Rest

[4] The rugby ball shape and peanut shape are different in the length of the minor axis. The minor axis of the rugby ball shape is longer than that of the peanut shape.

All organs involved in swallowing were constructed in a three-dimensional manner based on CT images of the head and neck of a 9-month-old body.

The CT images of the head and neck were subjected to threshold processing for CT values[5] to automatically identify bones and spaces, with insufficient areas arranged with additional anatomical knowledge. The bones and spaces were used as markers to visualize soft tissues, including the thyroid cartilage, cricoid cartilage, tongue, and soft palate. This operation provided three-dimensional shape data on swallowing-related organs in the 9-month-old body at rest (Figure 3).



(a) CT image

(b) 3D construction of bones

(c) 3D construction of spaces

(d) 3D construction of organs (magnified)

Figure 3. Method of creating surface geometries of organs based on CT images from a 9-month-old child

Three-dimensional shape data were output in a Standard Triangulated Language (STL) format, in which surfaces of organs[6] were represented as sets of triangles. They were used as the initial shapes at the start of swallowing.

(2) Arrangement of Particles for Analysis on Three-dimensional Shape Data

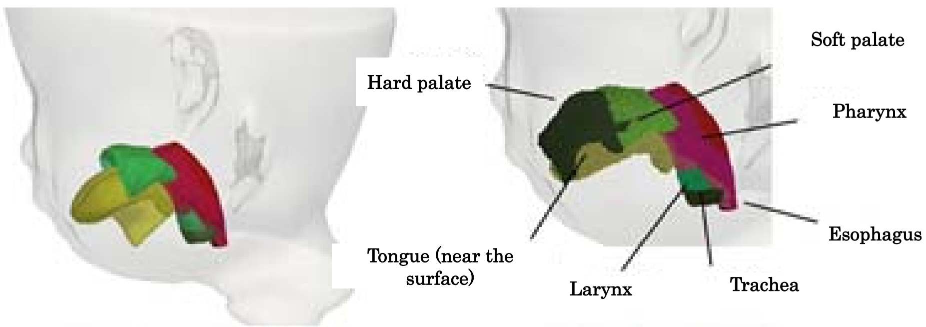
Calculation methods for numerical simulation include mesh and particle methods. A mesh method is more excellent in analyses of small deformations such as deformations of metal, while particle methods are better for analyses of large

[5] In CT, the density of tissues is expressed as CT values, which are relative values. CT values are based on water (CT value of 0) and air (CT value of 100) and the CT value of bones is approximately at least 300. Therefore, threshold processing for CT values allows relatively easy automatic identification of bones and air.

[6] Three techniques for representing solids on a computer are wireframe, surface, and solid. The technique for representing only the surface using surfaces with the inside hollowed up is called surface and is suitable for representing complex geometries. It is used for a wide range of purposes, including design of the body of a car.

deformations such as those of rubber. A particle method was selected for airway obstruction simulations, because soft tissues of the living body from the mouth to the pharynx undergo large deformation during swallowing.

Particles for analysis using the particle method were arranged in a three-dimensional grid pattern within the region of the three-dimensional shape data at the start of swallowing (Figure 4). A total of 114,215 particles (each with a diameter of 0.6 mm) were arranged in the shape model for the 9-month-old child with consideration of accuracy and cost of calculation.



(a) Surface meshes and particles represented

(b) Magnified view (only particles represented)

Figure 4. Shape models for simulation created based on CT images

(3) Analysis of Swallowing Movement

An optimal examination of swallowing is a fluoroscopic examination that takes X-ray images of the actual process of swallowing of X-ray contrast medium (videofluoroscopy of swallowing). This examination is a standard method for clinical diagnosis of swallowing disorder and may also be used for research if it meets requirements. At the same time, cases of videofluoroscopy of swallowing in healthy infants have been rarely reported due to concerns of radiation exposure; however, a videofluoroscopic image showing that a 9-month-old child (a 9-month-old healthy girl)[7] swallowed liquid[8] was available and therefore used.

An analysis of this videofluoroscopic image of swallowing indicated that the

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[7] It is likely that there are few gender-related differences in growth between males and females aged nine months.

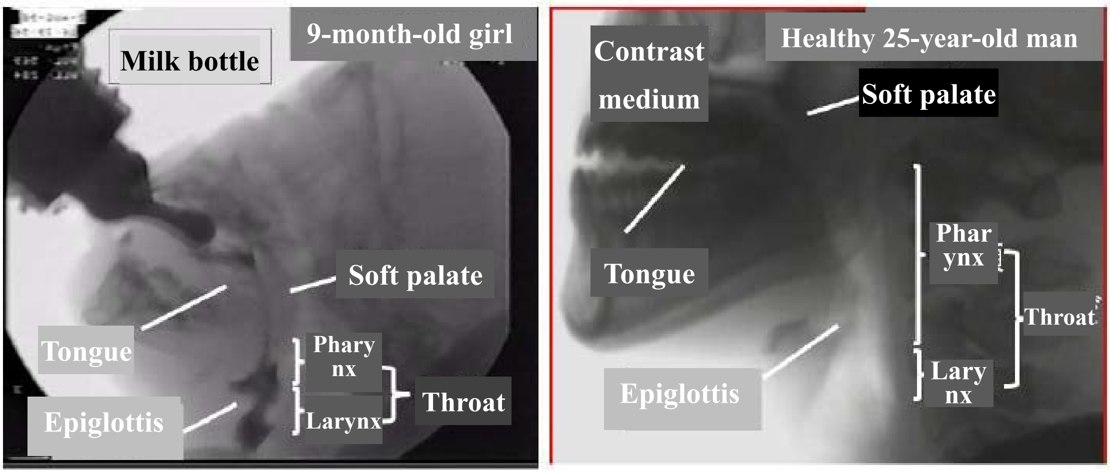
[8] Hiroyuki Haishima, et al. "Observation of swallowing movement in a nine-month-old child with an X-ray TV – comparison of swallowing between infants and adults" Japanese Journal of Dysphasia Rehabilitation, Vol.1 p33-44, 1997 (in Japanese)

swallowing movement in the 9-month-old child was characterized as follows:

(a) She held liquid in the hypopharynx but not in the mouth.

(b) Swallowing movement was initiated when a certain volume of liquid was held in the hypopharynx.

This confirmed that swallowing movement was initiated in a 9-month-old child after a food bolus was held, whereas swallowing movement is initiated in an adult (a healthy 25-year-old man) before the food bolus enters the pharynx (Picture 1). The analysis of the videofluoroscopic images of swallowing confirmed that the timing of the initiation of swallowing movement was different between a 9-month-old child and an adult.



Picture 1. Videofluoroscopic images of swallowing (left: 9-month-old child, right: an adult)

Subsequently, the movements of the organs after the initiation of swallowing movement were analyzed. The results showed that the direction and timing of the movement of the organ related to swallowing, such as the tongue, soft palate, pharyngeal wall, and epiglottis, that is, the pattern of swallowing movement, was the same between the 9-month-old child and the adult.[9]

(4) Creation of the Model of Swallowing Movement

Based on the analysis of swallowing movement, the movement pattern was modeled using the same method as conventional Swallow Vision®. More specifically,

[9] Because the existing movement model in Swallow Vision® is based on the swallowing pattern of a healthy adult, it was confirmed that the movement model incorporated in Swallow Vision® was available for airway obstruction simulation in an infant.

swallowing movement was reproduced by forcibly displacing the regions with active movements, such as muscles, represented by particles arranged in the living body model (forced displacement) with time. Other regions of the living body were defined as elastic bodies like rubber and were allowed to passively move on with forcibly displaced regions.

2.2.2 Creation of Numerical Models of Toys

(1) Selection of Toys

Based on the results from the questionnaire survey conducted among parents/guardians by the Investigation Commission, objects that were of the same size when viewed from any angle, such as spheres and cubes, flat objects, and elongated objects such as cuboids, with which aspiration occurred more commonly, were selected as shapes of toy models. In addition, a pacifier-shaped toy, consistent with the case filed, was also selected. For the sphere, sphere-like shapes such as hemisphere and ellipse were also chosen.

The sizes ranging from 6 to 20 mm were selected based on the results of the above questionnaire survey and reported cases in Injury Alert.

Two different types of materials, rigid and elastic bodies, were selected.

(2) Measurement of Shapes and Sizes

For the sphere, hemisphere, ellipse, cuboid, or cube, the diameter, major diameter, or minor diameter was measured. For the pacifier-shaped toy with a complex shape, data on the shape and size were acquired by imaging with an industrial CT device.

(3) Young's Modulus

A Young's modulus of toys was used as a measure of hardness. A total of three types of indenters pressed into samples for measurement, two spherical indenters (φ20 mm, φ1 mm) and a plate indenter, were used, depending on the hardness and shape of samples. The Young's modulus measuring instrument SOFTMEASURE HG-1003 SL (Horiuchi Electronics) was used for measurement.

The instrument was secured to a stand with a sample placed directly below the instrument. Spherical samples or samples that became unstable depending on orientation were held with clay and measured (Figure 5). In doing so, it was made sure that the plasticity of clay did not affect measurements.

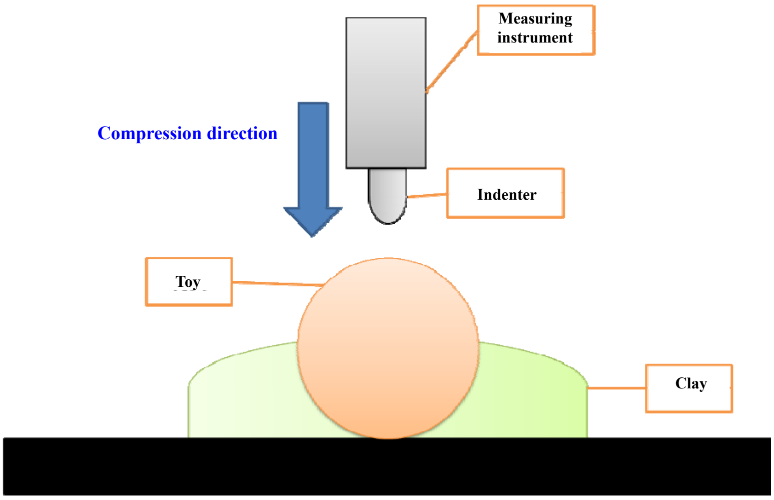


Figure 5. Method of measurement of the Young's modulus (image)

Since this instrument measures Young's moduli based on the load and displacement between a sphere and a plane, samples with a plane were measured using a spherical indenter and spherical samples were measured using a flat indenter. Soft samples were measured at a compression rate of 2 mm/sec. The maximum load selected was 1 N or 2 N, a standard load. For extremely soft samples, however, smaller load values were selected to prevent invagination of indenters from interfering with measurement.

It should be noted that published nominal values were used for hard samples (glass, plastic), because this instrument was not suitable for measuring hard samples with only small displacements.

(4) Measurement of Coefficient of Friction

Coefficient of friction, which is a measure for the status of the interface between a living body and a toy, was measured ex vivo due to extreme difficulty in performing experiments in the mouth or pharynx.

Hydrophilic polyvinyl alcohol (hereinafter referred to as "hydrophilic PVA"), which has similar physical properties to mucosa of the living body, was taken out from preservative solution and weighed in an adequately wet state. A sample was then placed on hydrophilic PVA, which, in turn, was sloped, and the angle at which the toy started to move was recorded. The coefficient of friction can be expressed as follows: $\mu = \tan\theta$, where μ is the coefficient of friction and θ is the angle of slope (Figure 6).

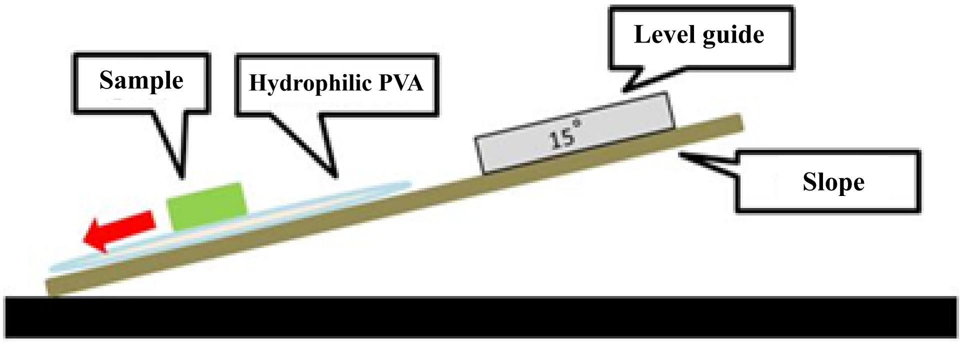


Figure 6. Method of measurement of the coefficient of friction

Measurement was repeated in triplicate for each sample and measurement results were represented as means of three replicates. Spherical samples were measured with two or more samples connected to prevent them from rolling. When a single toy potentially had two or more planes with different coefficients of friction, all of the planes were measured.

(5) Measurement of Coefficient of Restitution

Coefficient of restitution is a measure for the relationship between a sample and a living body when the sample collides with the living body at high speed. Due to difficulty in performing measurement in the mouth or pharynx, a 10-mm thick slice of the tongue of a pig, which is similar to that of a human, was placed on an aluminum tray and dropped from a height of approximately 150 mm while imaged with a high-speed camera. Imaging speeds of 1000 fps[10] and 250 fps were used. The experiment was repeated twice or more for each sample and performed in different orientations for samples other than spherical samples.

(6) Modeling of Toys

Three-dimensional shape data (in the STL format) of the sphere, hemisphere, ellipse

[10] Stands for frames per second. A unit that indicates smoothness of a motion picture and describes how many times per one second images or screens were updated. For example, a motion picture at 1000 fps consists of 1000 still images per one second and is played by switching images at intervals of 0.001 seconds.

(rugby ball shape and peanut shape), cuboid, cube, block toy, and marble shape were generated based on measured values on CG software. Particles for simulation analysis were arranged along a curved surface of toys, not in a three-dimensional grid pattern, for toys with the curved surface to improve the reproducibility of the surface of toys.

For the pacifier-shaped toy, in contrast, CT scans were taken and the CT data were used to obtain three-dimensional shape data for efficiency. Particles were arranged within this area in a three-dimensional grid pattern.

The number of particles arranged depended on the size of toys; for example, a total of 18,950 particles were arranged for a sphere with a diameter of 20 mm.

The density of toys was 1.0×10^3 kg/m^3 and the coefficient of friction ranged from 0.05 to 0.2, as determined by measured values.

2.2.3 Simulation Analysis Using the Particle Method

This simulation analyzed the motion of particles representing the living body and toys using the particle method. An overview of the simulation analysis using the particle method is provided below.

In the simulation analysis using the particle method, the living body was defined as an elastic body that became deformed when subjected to external force (Mooney-Rivlin hyperelastic body[11]), like rubber. When a part of the living body actively moves during movement, other parts are passively moved or deformed under pushing or pulling force. In addition, viscous force is added to provide a more stable analysis. Swallow Vision® uses this method for the modeling of swallowing movement. The same method was used for this simulation.

In contrast, hard toys that underwent only negligible small deformation when subjected to force from the living body, such as plastic toys, were defined as rigid bodies. Handling such toys as rigid bodies without respect to deformation reduces the time required for analysis. Other soft toys were handled as elastic bodies.

Toy models are moved by gravity and contact force from the living body. Contact force consists of normal force[12] and frictional force, which are applied to both the living body and a toy at the contact point between the living body and the toy. The magnitude of

[11] A hyperelastic body model that was devised based on the extension ratio from a phenomenalistic viewpoint and is used to simulate rubber or soft tissues of a living body.

[12] A force that acts on the surface of an object to interfere with its movement. A component perpendicular to movement is normal force and a component parallel to movement is typically frictional force. (“Kojien” 6th edition, edited by Izuru Shinmura, Iwanami Shoten, 2008)

frictional force is determined by the magnitude of normal force and coefficient of friction.
A detailed description of the simulation analysis using the particle method is provided below.

(1) Particle Method

The particle method is a type of the Lagrange method in which calculation points are moved with movement or deformation of objects. Swallow Vision® uses the moving particle simulation (MPS) method, a type of the particle method. The MPS method is a method in which governing equations are discretized by using inter-particle interaction models corresponding to differential operators.
For the purpose of this analysis, the infant's human body was defined as an elastic body (Mooney-Rivlin hyperelastic body) and toys were defined as elastic or rigid bodies. Toy models, analytes of interest, were also divided into groups of fine particles and the movement of each particle was simulated over time.

(2) Analysis of Elastic Bodies

The movement of each particle defined as an elastic body was analyzed using the following equation of motion:

$$\rho \frac{\partial \mathbf{v}}{\partial t} = \mathbf{f}_{\text{elastic}} + \mathbf{f}_{\text{artificial}} + \mathbf{f}_{\text{viscous}} + \mathbf{f}_{\text{contact}}$$

where ρ is the density and $\mathbf{v}$ is the velocity vector. The terms on the right side of the equation are the elastic force, artificial potential force, viscous force, and contact force with other structures (human body or toys), respectively. The elastic force, artificial potential force, and viscous force are all internal forces, whereas the contact force (as described later) is an external force.
In this simulation, the Hamiltonian MPS method[13] was used for analysis of elastic force. Elastic force is a restoring force that acts to restore deformation exerted inside a deformed elastic body to return the elastic body to its original shape. In this method, the governing equation of an elastic body

[13] An expanded version of the MPS method to make it applicable to non-linear elastic bodies, which are elastic bodies in which deformation does not bear a proportionate relationship to stress.

$$\rho \frac{\partial \mathbf{v}}{\partial t} = -\frac{\partial W}{\partial \mathbf{x}}$$

is transformed to formulate the elastic force per unit volume with the following equation:

$$\mathbf{f}_{i,\text{elastic}} = \rho \frac{\partial \mathbf{v}}{\partial t} = \sum_{j \neq i} (\mathbf{F}_i \mathbf{S}_i \mathbf{A}_i^{-1} \mathbf{r}_{ij}^0 + \mathbf{F}_j \mathbf{S}_j \mathbf{A}_j^{-1} \mathbf{r}_{ij}^0) w_{ij}^0$$

$$\mathbf{F}_i = \left[\sum_j \mathbf{r}_{ij} \otimes \mathbf{r}_{ij}^0 w_{ij}^0 \right] \mathbf{A}_i^{-1}$$

$$\mathbf{A}_i = \sum_j \mathbf{r}_{ij}^0 \otimes \mathbf{r}_{ij}^0 \, w_{ij}^0$$

where W is the strain energy function, $\mathbf{r}$ is the relative position vector, $\mathbf{F}$ is the deformation gradient tensor[14], and w is the weight function for MPS method, and the superscript 0 represents the status at the initial point.

In this simulation, the Mooney-Rivlin model given by the following equation was applied as a dynamic model:

$$W = C_1^{\text{MR}} (\tilde{I}_1 - 3) + C_2^{\text{MR}} (\tilde{I}_2 - 3) + D_1 (J - 1)^2$$

where C_1^{MR}, C_2^{MR}, and D_1 are the material constants[15], J is the third invariant[16] (percent volume change), and $\tilde{I}_1$ and $\tilde{I}_2$ are the reduction invariants of the right Cauchy-Green deformation tensor.

In addition, a supplementary force to suppress specific displacement modes or vibrations with the Hamiltonian MPS method (artificial potential force) and a viscous force similar to that used to decrease the particle velocity to stabilize calculation in fluid analysis based on the MPS method were defined by the following equations:

[14] When there are two vector quantities and the component of one vector is expressed as the linear form of the other vector component, an overall quantity for connection between them is called gradient deformation tensor. Stresses or strains inside a solid are expressed as tensors. ("Kojien" 6th edition, edited by Izuru Shinmura, Iwanami Shoten, 2008)

[15] Constants or physical property values to describe properties of materials.

[16] An invariant is a scalar quantity that is associated with vectors or dyadic tensors and is not affected by changes in coordinates. (Compiled by Japan Association for Nonlinear CAE and written by Takashi Kyoya, "Continuum Mechanics", Morikita Publishing, 2008)

$$\mathbf{f}_{i,\mathrm{artificial}} = \sum_j \left(C_i^{\mathrm{art}} (\mathbf{r}_{ij} - \mathbf{F}_i \mathbf{r}_{ij}^0) + C_j^{\mathrm{art}} (\mathbf{r}_{ij} - \mathbf{F}_j \mathbf{r}_{ij}^0) \right) w_{ij}^0$$

$$C_i^{\mathrm{art}} = \frac{\hat{E}_i d}{\sum_j \left| \mathbf{r}_{ij}^0 \right|^2 w_{ij}^0}$$

$$\mathbf{f}_{i,\mathrm{viscous}} = \rho \nu^{\mathrm{ela}} \frac{2d}{\lambda n^0} \sum_j (\mathbf{v}_j - \mathbf{v}_i) w_{ij}^0$$

where *Ei* is the coefficient of a supplementary artificial potential power determined based on a Young's modulus of an object, *d* is the space dimensionality, and λ and n^0 are the constants for the MPS method.

(3) Analysis of Rigid Bodies

Because rigid bodies are objects that do not deform, the movement of each particle was not calculated, but the translational movement[17] and rotational movement of the gravity center position of a rigid body as a whole was calculated. The momentum **P** and the angular momentum [18]**L** of a rigid body are described by the following equations:

$$\mathbf{P} = M\mathbf{v}$$

$$\frac{d\mathbf{P}}{dt} = \mathbf{F}$$

$$\mathbf{L} = \mathbf{I}\boldsymbol{\omega}$$

$$\frac{d\mathbf{L}}{dt} = \boldsymbol{\tau}$$

17 Movements of place systems or rigid bodies that consist only of the same parallel translation at each place without rotation or deformation. Arbitrary movements of rigid bodies can be divided into translational and rotational movements. ("Kojien" 6th edition, edited by Izuru Shinmura, Iwanami Shoten, 2008)

18 Moment of momentum regarding a certain point. For rigid bodies, its magnitude is expressed as the product of the moment of inertia around the axis of rotation and the angular velocity. ("Kojien" 6th edition, edited by Izuru Shinmura, Iwanami Shoten, 2008) where M is the mass of the rigid body, $\mathbf{v}$ is the translational velocity of the rigid body, $\mathbf{F}$ is the external force applied to the rigid body, $\mathbf{I}$ is the inertial tensor, $\boldsymbol{\omega}$ is the angular velocity[19], and $\boldsymbol{\tau}$ is the torque produced by the external force applied to the rigid body.[20] Since the rigid body is expressed as a group of particles, the external force $\mathbf{F}$ and torque $\boldsymbol{\tau}$ can be determined based on the external force applied to the particles that compose the rigid body.

(4) Contact Analysis

Contact force consists of normal force and frictional force, which are generated by contact between a wall surface of a living body and food bolus or between a wall surface and another wall surface of a living body.

Contact analysis using the conventional particle method involves an issue that exposure of a wall to force causes particles to get stuck among wall particles, resulting in the eruption of asperities on the wall surface. A solution to this issue is the metaball method in which a group of spheres with a concentration distribution is defined and a wall surface is defined by a certain threshold. This study applied a method that involves smoothing of a wall surface expressed by particles using the metaball method. However, in the contact analysis, elastic body particles were handled as spheres for stabilizing the analysis.

In addition, mucosal surfaces of the tongue or pharynx are highly elastic and soft, and therefore less repulsive. On the other hand, the less repulsive nature is not easy to simulate in a contact analysis. A penalty method that uses only springs allows a relatively stable analysis, but the coefficient of restitution is set only to 1 and cannot be adjusted. On the other hand, a penalty method that uses springs and bumpers involves spring and bumper coefficients given in a trial-and-error approach.[21] In addition, an impulse-based method, in which calculations are made based on conservation of momentum and coefficient of restitution, may involve unstable analyses or sneaking-through in contact with multiple objects. Thus, although any method has good and bad points, this simulation used a penalty method using springs in combination with an impulse-based method to simulate a less repulsive nature in a

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[19] Angle of rotation of an object undergoing circular motion per unit time. ("Kojien" 6th edition, edited by Izuru Shinmura, Iwanami Shoten, 2008)

[20] The magnitude of the ability of rotating an object. ("Kojien" 6th edition, edited by Izuru Shinmura, Iwanami Shoten, 2008)

[21] Running simulations with varying values assigned to the spring and bumper coefficients to check for consistency with actual phenomena.

simplified manner.

(5) Parameters Used for Analyses

Numerical simulations often handle soft tissues of a human body as incompressible non-linear elastic bodies. Therefore, this simulation defined a human body as a Mooney-Rivlin hyperelastic body. In addition, the compressibility factor D_1 of 1 [MPa] was selected to control changes in volume. A ratio of material constants of Mooney-Rivlin hyperelastic bodies as soft tissues of the human body (C_1^{MR} and C_2^{MR}), a C_1^{MR}/C_2^{MR} ratio, is often set to 1. This simulation also used this ratio to determine the C_1^{MR} and C_2^{MR} values based on the Young's moduli of the organs.

The measurement of Young's moduli of internal organs such as the mouth and pharynx is difficult for ethical reasons and the measurement of physical properties of soft tissues during swallowing is also extremely difficult for technical reasons, with no reported cases identified. This simulation used physical properties during speech and literature values from numerical simulations of speech as references.

There has been no report in which the coefficient of friction of the tongue or pharynx was quantitatively measured and actual measurement in infants is further difficult. At the same time, because infants appear to secrete much saliva, resulting in a small coefficient of friction, a coefficient of friction ranging from 0.05 to 0.2 was selected (Table 1).

The time step Δt of 2.5×10^{-6}[s] and initial interparticle distance l_0 of 0.6×10^{-3} [m] were used.

Table 1. Specifications of analysis and analysis time

Analytical parameters	
Time step Δt[s]	**2.5×10^{-6}**
Initial interparticle distance l_0 [m]	**0.6×10^{-3}**
Number of particles	
Living body (9-month-old boy model)	**114,215**
Foreign substance (20-mm ball)	**18,950**

Number of simultaneous calculations	**Calculation time**
One analysis (parallel calculation)	**20 hours**
Six analyses (simultaneously)	**85 hours (one analysis)**

Intel core i7-3970X (6 core HT)

Physical properties of a living body		
Density [kg/m^3]		**1.0×10^3**
Young's modulus [Pa]	**Tongue**	**2×10^4**
	Soft palate and pharynx	**1×10^4**
	Larynx	**4×10^3**
	Epiglottis	**2×10^5**
Compressibility factor D_1 [Pa]		**1×10^6**

Foreign substance (toy)	
Density [kg/m^3]	**1.0×10^3**
Young's modulus	**None (rigid body)**
Coefficient of friction	**0.05, 0.1, 0.2**

2.2.4 Presentation of Analysis Results

Although the movements of a living body and toys are presented as groups of particles in the particle method, the surfaces of the living body and toys were presented using a three-dimensional CG to enhance visibility in this simulation.

More specifically, the geometries of a living body and toys at the start of swallowing were expressed with multiple triangles based on three-dimensional shape data (in the STL format). The geometries of the living body and toys were reconstructed at each time during swallowing movement by moving each vertex of these triangles in association with the movements of particles obtained from analysis.

The conventional Swallow Vision® used radial basis function (RBF) interpolation to associate particles for analysis with each vertex of triangles for presentation of geometries. The RBF interpolation is a widely used method for generating a smooth function in a space with RBF functions based on point group data as input values.

However, in this simulation, it was difficult to apply the RBF interpolation, because of a high spatial resolution for analysis and a large number of particles. Therefore, Koshizuka's method[22], rather than the RBF interpolation, was applied. This method is a method in which a weight function used for analysis by the particle method is used to move the vertices of three-dimensional shape data representing the initial shape of an object. In this simulation, a unique change was made to adjust a parameter called radius of influence, as appropriate, in order to ensure that the vertices of three-dimensional shape data were not outside the radius of influence of particles.

3. Airflow Simulation

One possible method to prevent asphyxiation even under the condition of obstruction by a toy is giving the shape of a toy twists, including making holes in a toy to establish an air passage. Therefore, simulations were performed to determine whether such twists avoided asphyxiation.

3.1 Creation of Shape Data of the Living Body and Toys

The shape data of a living body was created using shape data from the 9-month-old child used for airway obstruction simulation. Analytical calculation was performed

[22] Seiichi Koshizuka "Particle method simulation – Introduction to physically-based CG" (in Japanese) Baifukan, 2008.

using SOLIDWORKS FlowSimulation® (hereinafter referred to as “FlowSimulation®”) provided with the 3D CAD software SolidWorks.

First, the shape data were converted to the STL file format and the number of meshes was reduced down to 5% of the original data for reading with FlowSimulation® (with a total number of meshes[23] of 13,502), with care to keep shapes from being too rough.

Next, the shape data were simplified to simulate pharyngeal obstruction-type choking. More specifically, the epiglottis was inverted to place a choking object at the back of the soft palate and above the epiglottis, the vocal cords within the larynx were omitted to establish a passage of airflow, and the area leading to the nasal cavity was kept open. Among the openings, the terminals on the side of the mouth and on the side of the nasal cavity were defined as inflow and the terminal on the side of the trachea was defined as outflow (Figure 7).

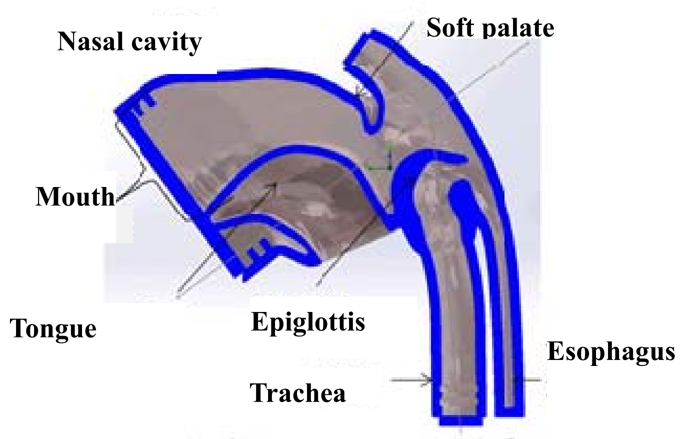


Figure 7. Shape data from a 9-month-old child (cross section from the right side)

In addition, the shape data of toys were also created on FlowSimulation®.

3.2 Setting of Analysis Conditions

FlowSimulation® involves setting the inflow surface and outflow surface. The openings in the mouth and nasal cavity were set as the inflow surfaces and had a defined environmental pressure (101,325 Pa). The opening on the side of trachea was set as the outflow surface and had a defined outflow volume flow rate of 80 mL/s[24] (Figure 8).

[23] Airflow simulations require quantification of phantom models (i.e., giving coordinates etc. to represent the models on a computer). The standard procedure is segmentalizing shapes into meshes, with the total number of segments being defined as the total number of meshes.

[24] Outflow volume flow rate was set based on a body weight. Based on the average standard body weight of a 9-month-old boy, a model for the living body’s shape, of 8.9 kg and with reference to a tidal volume

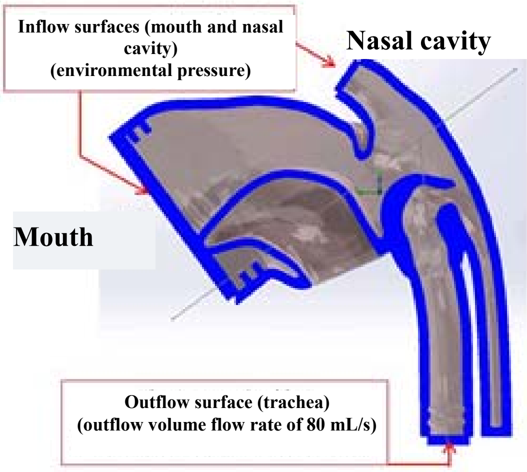


Figure 8. Setting of the inflow surfaces and outflow surface

In addition, analysis calculation was performed with consideration of gravity (Y: -9.81 m/s^2).

FlowSimulation® involves setting the conditions for ending analytical calculation (goals), consisting of surface goals for the entire calculation domain and surface goals for the inflow and outflow surfaces. In this analysis, static pressure, total pressure, mass flow rate, and velocity were set for the global goals and static pressure, total pressure, volume flow rate, and velocity were set for the surface goals for each of the three surfaces, that is, the surfaces in the mouth and nasal cavity selected as the inflow surfaces and the surface in the trachea selected as the outflow surface. It should be noted that mass flow rate was included in the global goals in FlowSimulation® to confirm that the mass of gas was maintained throughout the entire calculation domain.

4. Fabrication of a Phantom (Human Model)

4.1 Purposes of Fabrication of a Phantom

Models simulating the human body or body organs are called phantoms. CT images from the 9-month-old child were used to fabricate a phantom that simulated the outer surfaces of the head and the chest-abdomen and the internal organs ranging from the mouth through the pharynx down to the lungs as faithfully as possible. The purposes of

of 80 mL in an individual weighing 9 kg according to Radford's nomogram (Radford, Edward P. "Ventilation standards for use in artificial respiration." Journal of Applied Physiology 7.4 (1955): 451-460.), the outflow volume flow rate was set assuming that one inspiration takes one second.

the fabrication are shown below:

(a) To visualize where a toy is lodged to cause choking to serve as an aid in getting an understanding of choking.
(b) To provide a clear description of actions to be taken in case of choking.
(c) To visually illustrate by an example twists to be given to toys to avoid choking.
(d) To produce toys having a structure that allows avoidance of choking and to test their effectiveness.[25]

4.2 Design

First, the face was fabricated to establish a whole profile and the mouth, pharynx, larynx, esophagus, trachea, and lung were then fabricated. The left half of the face had a detachable structure so that the mouth, pharynx, and larynx were directly visible from the outside. Details are provided below.

To facilitate an understanding of where a toy was lodged among the internal spaces of the pharynx and larynx, the walls of the spaces of the mouth, pharynx, larynx, esophagus, and trachea were made transparent.

To provide a clear description of actions to be taken in case of choking, the head and neck, as well as the shoulder, chest, and abdomen, were fabricated and the inner cavity of the chest was provided with the trachea and lung. An Ambu bag[26] for children for medical use was used as the lung with consideration of the expiratory volume of infants.

For the fabrication of the phantom, CT images of the head and neck from the 9-month-old child used for the creation of simulations were used as fundamental data.

Because morphological information of the chest-abdomen was not included in the CT images of the head and neck, it was newly generated and the ratio of the chest-abdomen to the head and neck visualized on CT was checked to ensure that the image of an infant was not disrupted (software used: Geomagic® Freeform®).

Next, the facial appearance of the base shape was deformed to avoid identification of the individual. After that, the left half of the facial appearance was designed to be detachable so that the relevant organs were directly visible.

Among the transparent organs, the pharynx, larynx, esophagus, and trachea were created based on the CT images. The mouth, which also served as a passage for

[25] More specifically, a suction experiment with bouncing balls with holes of different sizes was performed to determine the effect of holes.

[26] A bag for medical use to deliver air (oxygen) through the mouth and nose in an emergency and other situations.

inserting a toy into the pharynx, was gotten into an open state that was deemed medically appropriate based on a trajectory of mandibular movement during mouth opening estimated from the jaw joint of the base shape.
Finally, the phantom was designed to exemplify toy choking by omitting unnecessary parts such as bones, cartilages, and vocal cords, closing the lower end of the esophagus, and diminishing in size the outer margin of the epiglottis to allow inversion (Figure 9).

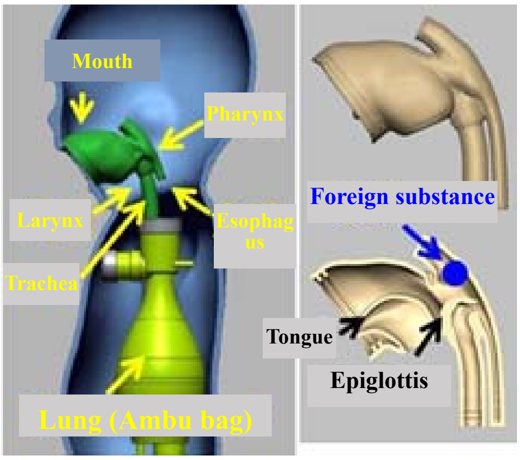
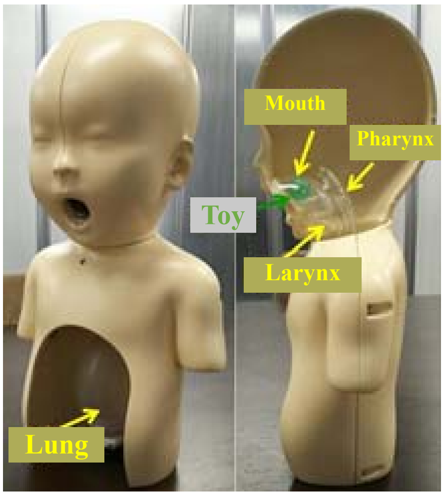


Figure 9. Overall cross-section of the phantom (left) and major relevant organs (right)

4.3 Method of Fabrication

The external surfaces of the head and neck and the chest and abdomen were made of nylon powder and fabricated by a lamination technique for 3D printer modeling. A 3D printer was used to produce resin molds of the mouth, pharynx, larynx, and esophagus and silicone was poured into them to make the models of these organs. These models were hollow, with their walls made of transparent silicone.
The size of the phantom is 140 mm in width, 190 mm in height, and 160 mm in depth for the head and face (in the open state) and 230 mm in width, 220 mm in height, and 110 mm in depth for the chest and abdomen (Picture 2).



Picture 2. Appearance of the phantom and cross section of the head and neck

4.4 Confirmation of Whether Toys can be Discharged

A bouncing ball was lodged in the pharynx and the back blow, chest compression, and Heimlich (abdominal thrust) maneuvers were performed. It was visually confirmed how the bouncing ball was pushed out into the mouth.

5. Production of Papercrafts

The location, size, and structure of the mouth, pharynx, larynx, trachea, and esophagus are not easy to understand. Therefore, the Investigation Commission first performed the airway obstruction simulation and fabricated the phantom to visualize the relevant organs and their movements. The Commission then produced a papercraft (a paper-based model) that was less expensive and expected to become widely used, because it believed that actually touching the model with hands would lead to realizing the location and size and developing a deeper understanding.

By actually assembling the model with our hands, we can realize the size and structure of the mouth, pharynx, larynx, trachea, and esophagus of an infant.

5.1 Design

The contour of the face and neck and the mouth, pharynx, larynx, esophagus, and trachea were designed so that they were of the actual size in a 9-month-old child when assembled. The spaces of the mouth and pharynx were designed to be directly visible and the pharynx was designed so that a ball approximately 15 mm in diameter could be lodged in it. The mouth was in an open state so that a ball could be inserted through the mouth to obstruct the space of the pharynx.

To enhance the potential for wide availability, the papercraft was made of A4 construction paper and the assembly illustration was made printable on A4 plain paper.

5.2 Method of Production

Based on three-dimensional shape data from the 9-month-old child used for phantom fabrication, a simplified three-dimensional model for the papercraft was made (software used: 3DCG software “Metasequoia®”) and a development drawing was made based on the data (software for creating development drawings “Pepakura Designer®”).

To allow assembly to be completed in a short time and in view of ease of assembly and ease of understanding of the structure while maintaining accuracy, the three-dimensional model for the papercraft was designed as follows.

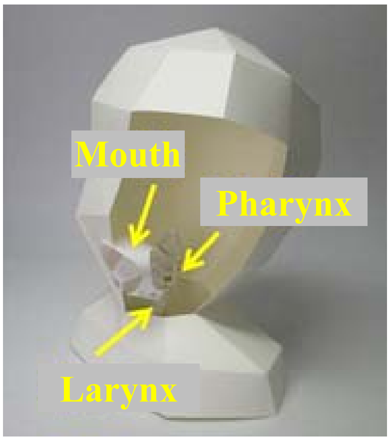
The left one-fourth of the face was left open to make the internal organs directly visible while ensuring the stability of the head as a model. The internal organs of the mouth, pharynx, larynx, and esophagus were created, with the mouth containing the tongue, the pharynx containing the soft palate, and the larynx containing the epiglottis. The left half of the mouth was cut out in a circle to make the spaces of the tongue and mouth directly visible. The left one-fourth of the pharyngeal wall was similarly cut out in a crescentic form to make the epiglottis and the inside of the pharynx directly visible. To incorporate the internal organs in the head, notches were made to insert and fix the organs[27] (Picture 3).

The development drawing contained margins to paste up for assembly and numbers for confirming positions to glue together.

5.3 Time Required for Production

When a total of ten individuals, including healthcare professionals and students, assembled the papercraft experimentally, the time required for assembly was approximately one hour. It was confirmed that this papercraft produced based on actual data was useful for realizing the actual size and also helped to understand the structure.

[27] See the attachments Assembly Illustration for “Model of the infant’s mouth and throat,” the Model of the infant’s mouth and throat, Assembly Illustration for “Model of the infant’s head,” and the Model of the infant’s head.



(a) Overview of the papercraft


(b) Mouth, pharynx, and larynx components

Picture 3. Final image of the papercraft

6. Movie Production

The Investigation Commission produced a movie titled "Protection of children from choking accidents," which included the results of the airway obstruction simulation as the main content. This movie tells that choking accidents are common accidents that can occur in households and contains examples of choking symptoms and descriptions of actions to be taken and preventive measures.

In this movie, a four-member family consisting of the father, mother, older brother, and younger brother appears in an environment in which airway obstruction accidents due to toys are assumed to occur in children and the younger brother aspirates and chokes on a toy when he is playing with it. The scene in which the siblings are playing with toys is live action. Shape data of the phantom was used to provide a description of the structure of related organs and the movies obtained from the airway obstruction simulation analysis were used for illustrating choking accidents by example.

For illustrating choking accidents by example, realistic computer graphics (CG) that met medical requirements were produced.

For actions to be taken at home in case of choking accidents (basic life support), the movie was used to show how a toy blocking the pharynx was brought to the mouth with the back blow maneuver, chest thrust maneuver, and Heimlich maneuver applied to the phantom.

Preventive measures, including keeping small objects 4 cm or smaller in size out of reach of children and learning actions to be taken in case of choking in case of emergency were presented.