Chapter 1

Risk Management in Swallowing Movement

A) Eating and Swallowing

There are various meanings of eating for humans other than to take nutrition. For instance, to prevent and treat illness, to express the feeling of love and anxious, to maintain human relations, to unravel a mental and emotional stress, to make others know a social status, to express a faith, and to enjoy a meal purely. The behavior of eating comprise not only as physical or physiological meaning, but mental, social, and cultural meanings. Thus the act of eating includes various values, and disorder of swallowing movements, which is referred to as dysphagia, have much influence on the quality of our life.

Usually, to eat or to drink starts with consciousness for ingestion and swallowing. Moreover, if food goes into throat from mouth, subsequent operation cannot be stopped by will, and it will go to stomach automatically. Drinking liquid or eating food is controlled by the voluntary action (which is possible with one's intention) and the involuntary movement (unconscious with an unrelated intention). The center of this control is located in the brain. The instructions about various swallowing functional operation take place from a cerebrum and the brain stem. These instructions get across to cranial nerves, and move the muscles of tongue and throat. On the other hand, from the sensory receptor of tongue and throat, the sensation of food is continuously sent to the brain.

A swallowing function is classified into five phases functionally and anatomically. That is, the phase to understand and prepare to eat food (recognition phase), the phase when saliva is mixed and food is made to swallow (preparation phase), the phase when food (bolus) press out to throat (oral phase), the phase when bolus pass

through pharynx (pharyngeal phase), and the phase when bolus pass to stomacl (esophageal phase). Thus, by operation called swallowing, a voluntary action anc an involuntary movement cooperate, and bolus goes to the stomach so that food anc liquid may flow smoothly.

Abnormalities in any portion of the network, the PC (brain), electric wire (nerve), and a motor (muscles), cause dysphagia. Since neurological diseases such as cerebral infarction and Parkinson's disease, affect the course from brain tc muscles, they cause dysphagia in many cases. Moreover, otolaryngological diseases, gastrointestinal diseases, orthopedic diseases may cause dysphagia. Furthermore, especially in elderly people, even if there is no illness, deglutition disorder may occur. About swallowing disorder caused by these diseases, research of the functional mechanism progresses in recent years, the pattern of an insufficiency is classified, and future prospects (prognosis), medical treatments, and rehabilitation methods are studying.

An important point when considering the risk of dysphagia is a phenomenon of aspiration which food may fall into lung and may cause pneumonia. Since a trachea

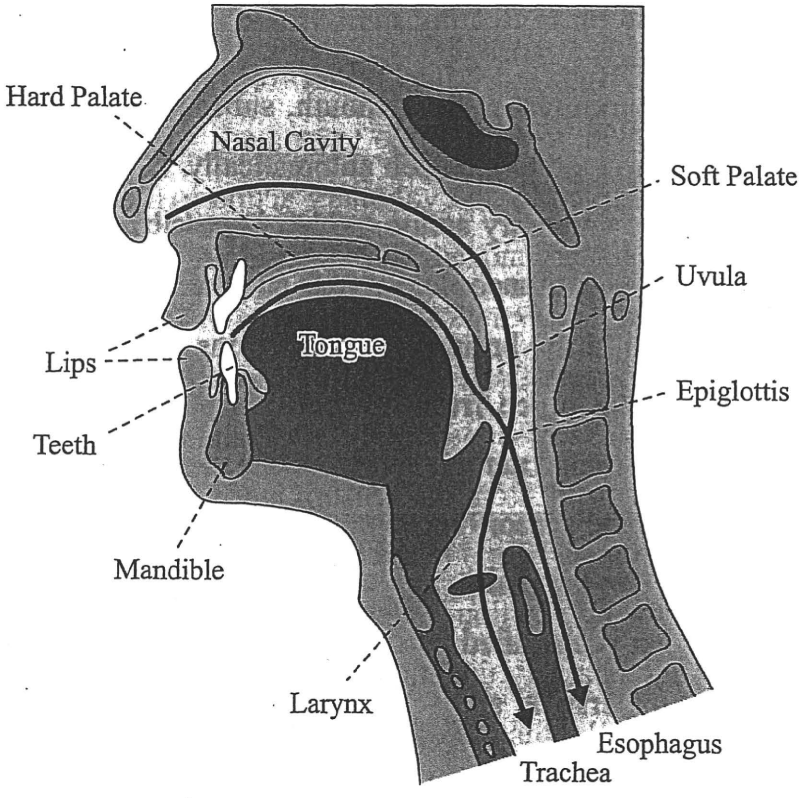

Figure 1.1 Structures involved in swallowing

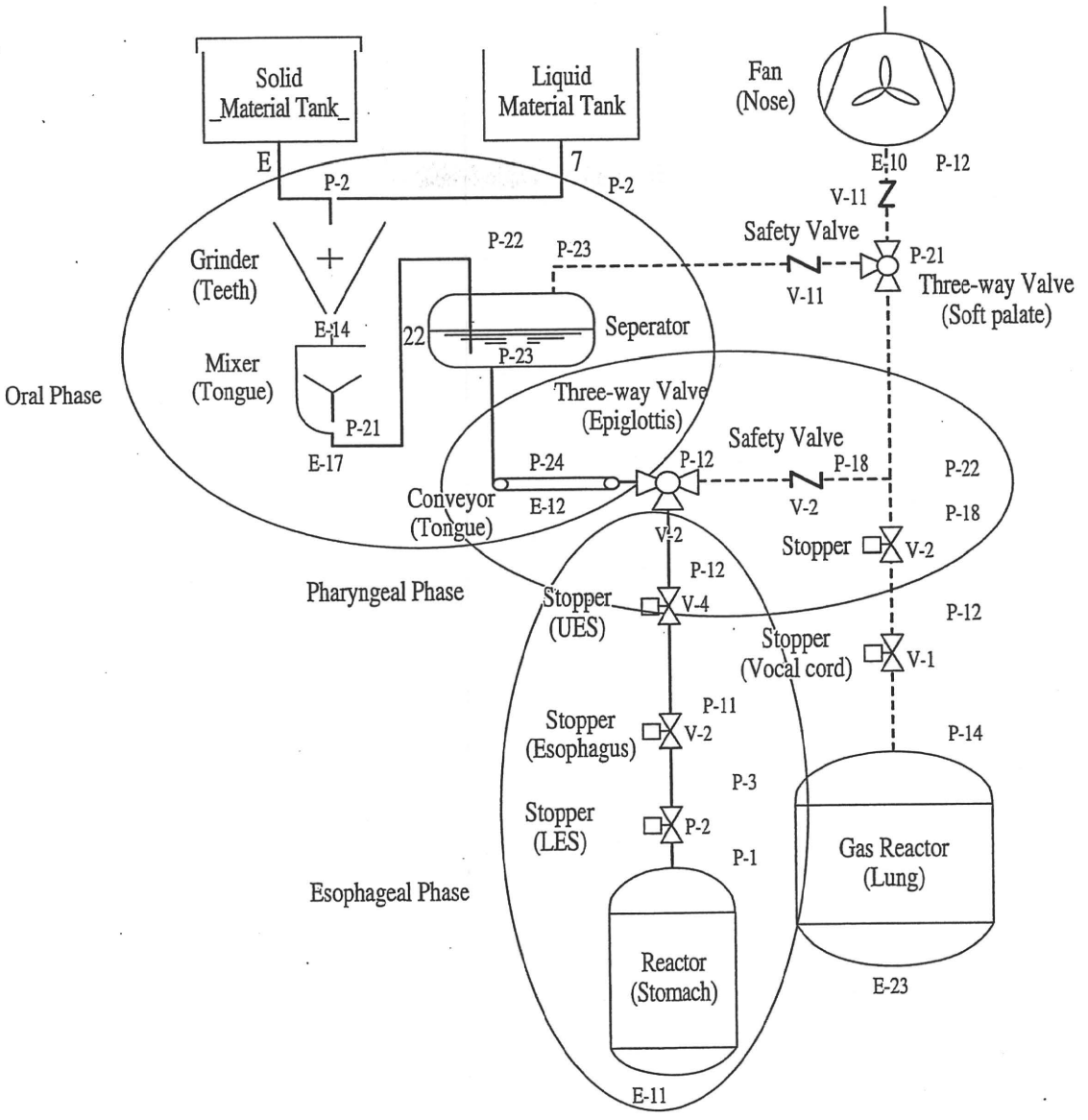

Figure 1.2 Piping and Instrumentation Diagram (P&ID) in swallowing

is a passage of breathing, suffocation and pneumonia are developed by aspiration. This type of pneumonia is called aspiration pneumonia, and has a feature which become seriously ill and chronic. With the disease which causes a swallowing difficulty, aspiration pneumonia determines life prognosis in many cases. Chronic aspiration occurred without obvious symptom (like coughing) is called silent aspiration and becomes frequent with age. In order to avoid the risk of aspiration, it is necessary to control traffic in the passage of air and food correctly in the case of swallowing movement. A swallowing difficulty is generated by the breakdown of this minute control mechanism. Conventionally, although HAZOP analysis was

Table 1.1 Swallowing process and P&ID

Swallowing Process		Process in Chemical Plant	Receptors
Recognition Phase	Recognization of food and start ingestion	**Material Tank** Receipt and investigation of food	Outlook Checker for volume Analyzer Thermometer
Preparatory Phase	Ingestion and mastication to form bolus	**Grinder and Mixer** Grind and mix of solid and liquid Produce mixture Pore chemical liquid (saliva) to the mixture	Thermometer Sensor for poison Sensor of volume Analyzer of grains Analyzer of texture
Oral Phase	Formation bolus and transfer from oral cavity to pharynx	**Conveyer** Transfer of bolos	Sensor for volume Sensor for conveyer
Pharyngeal Phase	Closure of upper and lower airway and transfer of bolus from pharynx to esophagus	**Seperator** Closure of upper and lower gas pipe Transfer of bolus mixture to solid/liquid pipe through two ducts (priform sinus)	Receptor for closure of gas pipe Receptor for opening for lquid/solid pipe
Esophageal Phase	Phase from entrance of esophagus to stomach	**Conveyer of liquid/solid mixture with two volves**	First volve (entrance volve to esophagus) Sensor for conveyer Second volve (exit volve to stmach)

a technique currently used for the risk assessment of a chemical plant, swallowing movement can be expressed as a chemical plant figure, which is the theme of this book. (Fig 1.1, 1.2, Tab 1.1)

B) Dysphagia and Aspiration Pneumonia

1) Incidence of Dysphagia and Aspiration Pneumonia

Among the patients with cerebrovascular disease it is reported that 22% to 65% of patients suffered from swallowing difficulty. Dysphagia is often associated with aspiration pneumonia, which results in an important factor for the life prognosis and QOL (quality of life) of a patient. Moreover, patients of aspiration pneumonia spend 21 to 40 hospital days, and medical expenses of 9,460 to 33,430 dollars are

estimated in U.S. Thus, the prediction and prevention of aspiration pneumonia is important from the field of medical cost and preventive medicine. However, the exact frequency of the swallowing difficulty and aspiration pneumonia was unknown in any country.

Then, we conducted large-scale investigation for medical institutions all over the country, the welfare institution for elderly people, and the home nursing station about the frequency of dysphagia, aspiration pneumonia, and the nutrition method. We collected the questionnaires of 50,607 examples from 2,867 institutions in total. Main purpose of this survey is 1) the frequency of patients with dysphagia, 2) the frequency of aspiration pneumonia, 3) the frequency of silent aspiration, and 4) nutrition method in patients with dysphagia. As a result, the frequency of patients with dysphagia is 28.5% in nursing home, 17.7% in-home visit, and 14.7% in hospitals (Fig 1.3, Tab 1.2). The frequency of acute aspiration pneumonia is 3.9 to 11.0% , and it is estimated that 1.15% to 1.60% of total patients in facilities suffered from aspiration pneumonia. Moreover, the past history of dysphagia is 56.3% in-home visit, 42.0% in hospitals, and 35.3% in nursing home. 5.6 to 11.7% of patients with aspiration pneumonia did not show signs of coughing or chocking, and these patients reveal silent aspiration. About half of dysphagia patients ingest orally, and nutrition route by PEG was mostly used for the patient who cannot carry out oral

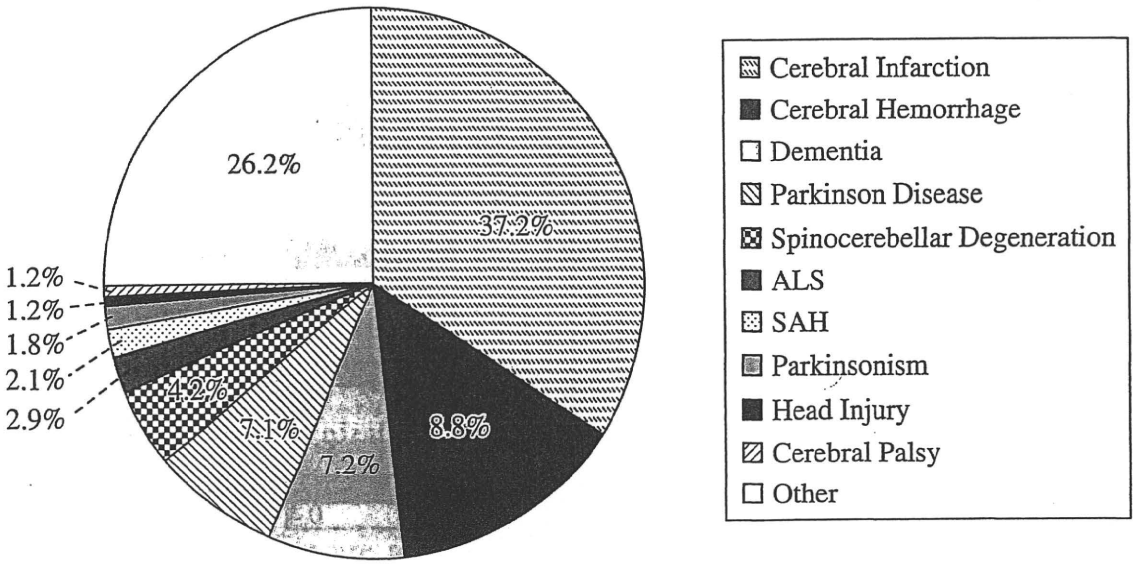

Figure 1.3 Cause of dysphagia (in-home service)

Table 1.2 Survey of dysphagia in Japan

	Hospital	Nursing Home	In-Home Care
Number of facilities	1,053	841	712
Number of all the patients	188,156	43,234	33,374
Number of patients with dysphagia	27,659	12,759	5,907
Dysphagia/All the patients (%)	14.7	29.5	17.7
Aspiration pneumonia (%)	1.60	1.15	1.40
Aspiration pneumonia/Dysphagia (%)	11.0	3.9	7.6
Aspiration pneumonia (past history) (%)	42.0	35.3	56.7
Silent aspiration (%)	11.70	7.63	5.58

ingestion (Fig 1.4, 1.5).

The age composition of the population in Japan increase gradually, and the rate of population aged 65 and over was 17.2% in 2000. It is estimated to reach to 26.9% in 2020 and to 32.3% in 2050. The prevalence rate of the disease which needs care with aging is also increasing. Especially, as a bedridden cause, cerebrovascular diseases forms about 40% of elderly people's bedridden cause, and has become the cause of reducing QOL. Stroke causes swallowing difficulty simultaneously in many cases, and prevention of aspiration and pneumonia becomes an important challenge for the medical person and the care worker.

The evaluation of dysphagia in consideration of disease recovery process is also an important viewpoint. Although the incidence of dysphagia after stroke varies

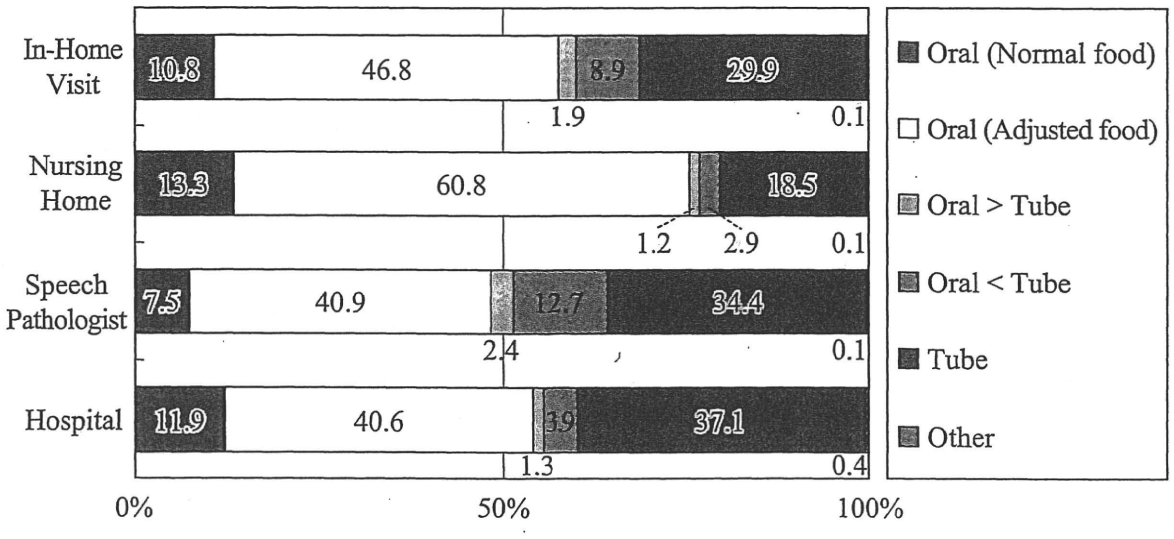

Figure 1.4 Route of nutrition

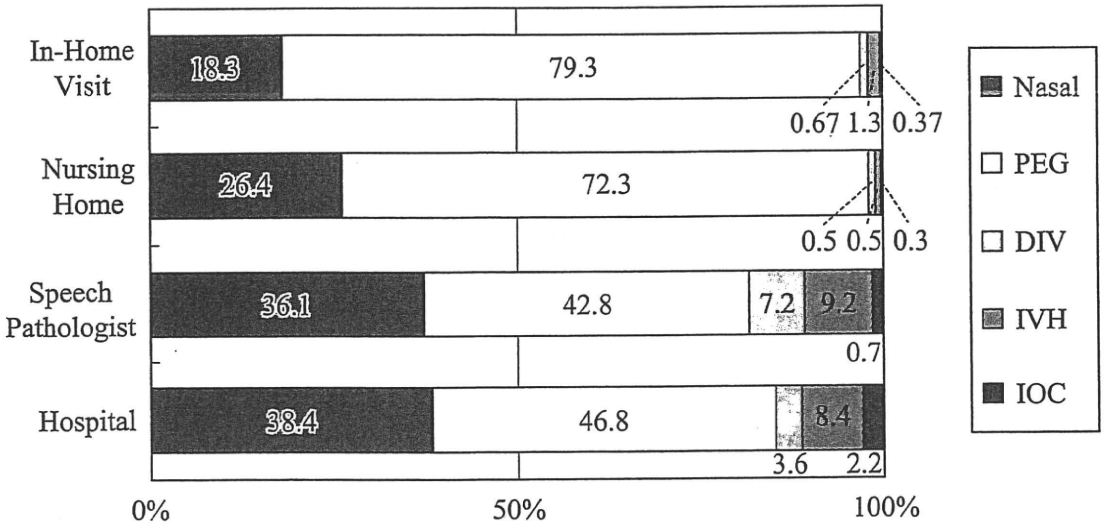

Figure 1.5 Route of tube feeding

according to reports, it is estimated from 22% to 65%. By videofluorographic study (VFSS) dysphagia is reported in 65% of patient with stroke within five days and in 80% within one week. In the acute phase of stroke, 51 to 73% patients with dysphagia result in aspiration, and it is reported that aspiration raises the relative risk of pneumonia 6.95 times. Since it takes into consideration that 34% of stroke patients is dead by pneumonia, the measure against dysphagia and aspiration is important also from the viewpoint not only of the life prognosis and QOL of a patient, but medical-expenses and cost efficiency. After an acute phase, 80% or more of patient with dysphagia is recovered within 2 to 4 weeks. According to the report of Smithard, the prevalence rate of dysphagia is 80% at onset, 27% on the 7th day, 17% after one month, and 11% after six months. In another analysis, incidence of aspiration pneumonia is reported 10.9 % in a week, 0.5 % in four weeks, and 0.2 % in 12 weeks after the onset of stroke. The most important point is the timing when dysphagia patient begin oral ingestion considering the risk of aspiration. In many cases whether oral ingestion is possible for a patient is determined by experience of doctor, nurse, or speech pathologist, and judgment may not be based on the evidence.

As riskfactors of aspiration pneumonia for patients with stroke, mechanical ventilation, multiple brain lesion, verteblobasilar lesion, deglutition disorder, abnormal chest X-rays are reported. Moreover, it is reported to be influenced by a consciousness level and the existence of tube nutrition. In this book our basic

investigation is focused on cases who can start oral ingestion in chronic phase of stroke, however, there are many cases who still remains tube feeding because of dysphagia and aspiration.

These data indicate that it is our important mission how correctly we can perform risk assessment and management of dysphagia in the future aging society.

C) Mechanism of Dysphagia and Risk Management

1) Mechanism of Swallowing Movement and Disorders

In HAZOP analysis, the first thing is to perform structured investigation of a movement process (WBS: creation of Work Breakdown Structure, after-mentioned). The process of swallowing movement can actually be expressed in chemical plant, as shown in the figures (Figure 1.1 and 1.2). The process of swallowing movement is classified functionally and anatomically into five phases. That is, the recognition phase in which we are going to understand and eat food, the preparatory phase in which we mix saliva and form bolus, the oral phase in which bolus is sent to the pharynx from the mouth, the pharyngeal phase in which bolus passes pharynx so that it may not go into a trachea, and the esophageal phase which bolus is transferred into stomach (Table 1.3). This process is roughly classified into ingestion (from recognition to preparation phase) and swallowing (from oral to esophageal phase). In ingestion conditions such as cognitive state, tabling, and oral care are involved, and in swallowing involuntary mechanism serves as movement mechanism.

Table 1.3 Five phases of swallowing movement

Recognition phase	Understand food and start ingestion
Preparatory phase	Ingestion and mastication to form bolus
Oral phase	Transfer bolus to pharynx
Pharyngeal phase	Transfer bolus through pharynx
Esophageal phase	Transfer bolus through esophagus

2) Swallowing Process

a) Preparatory Phase

The phase to prepare bolus, and there are three steps, predation, digestion, and the bolus formation.

b) Oral Phase (Figure 1.6)

After bolus is formed, in order to transport it to the pharynx from the mouth, various movements start in 0.5 seconds. Vocal cords are adducted first, operation of tongue and hyoid starts, and lips close. Furthermore, vocal folds are closed and UES opens. Operation of tongue is important in oral phase and makes bolus move. Tongue margin is firmly attached to the hard palate, and bolus is sent in. External tongue muscle is contracted at the moment of swallowing so that bolus may be pushed out backward (to pharynx). A hyoid is elevated by this motion to the front. The rear tongue is carried out by the palatoglossus muscle on elevation. Simultaneously, movement behind tongue makes hyoid kickback on elevation to the position at the angle of mandible, and this elevated position is maintained during swallowing movement. Closing of the nosopharynx is completed by a velar elevation. Moreover, airway obstruction also starts in oral phase simultaneously for laryngeal protection. The blockade of both vocal cords and vocal folds are also important.

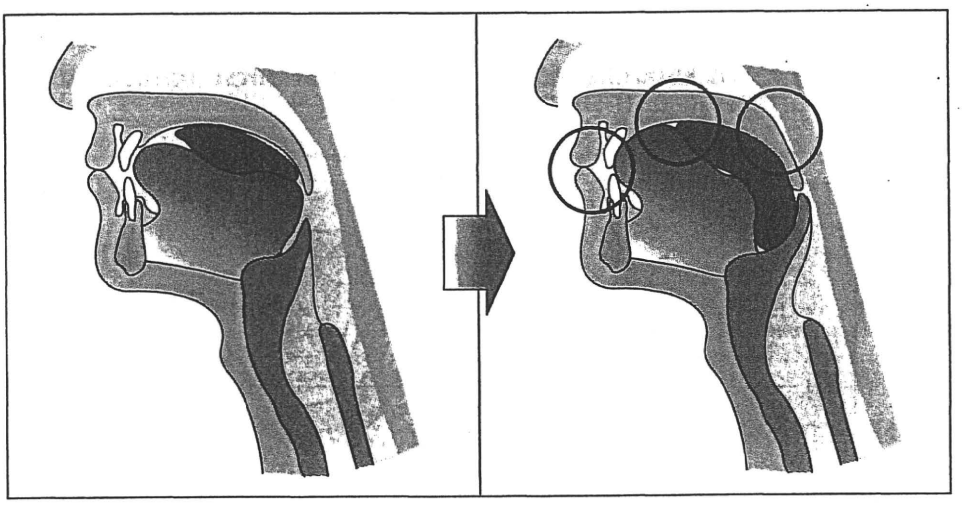

Figure 1.6 Bolus in oral phase
Circles are points to produce pressure.

c) Pharyngeal Phase (Figure 1.7)

Pharyngeal phase is a process where most organs are involved and operated dynamically. Various organs, such as epiglottis, pyriform sinus, hyoid, thyroid and annular cartilage, larynx, and laryngeal wall, move continuously. Pharyngeal muscles will be carried out on elevation and will be shortened when bolus arrives. With movement of thyroid cartilage and annular cartilage, larynx holds on elevation to the front upper part. The epiglottis closes the upper part respiratory tract entrance with laryngeal elevation, and bolus is guided to the esophagus instead of to the respiratory tract. Elevation of larynx (2 to 3cm) produces negative pressure in lower pharynx part. Bolus moves into the pharynx in the portion of epiglottic vallecula from sublingual region, and it avoids going to respiratory tract. The respiratory tract protection mechanism are shown in Table 1.4. The constrictor muscle of pharynx shortens the pharynx narrowly simultaneously, and positive pressure is produced by nose pharynx closing by the velum. The contraction time of this pharyngeal muscle is not based on bolus size. Bolus goes to the superior pyriform sinus of the bottom pharynx, and joins in the UES.

Bolus remaining at tongue base, epiglottic vallecula, and pyriform sinus after the end of a swallowing movement is called pharyngeal residues. It is important at bedside to take medical history of the existence of a feeling of remains in pharynx. When remains are seen in VFSS, we should check the existence of a feeling of residues. Furthermore, it should be confirmed whether these remains disappear by

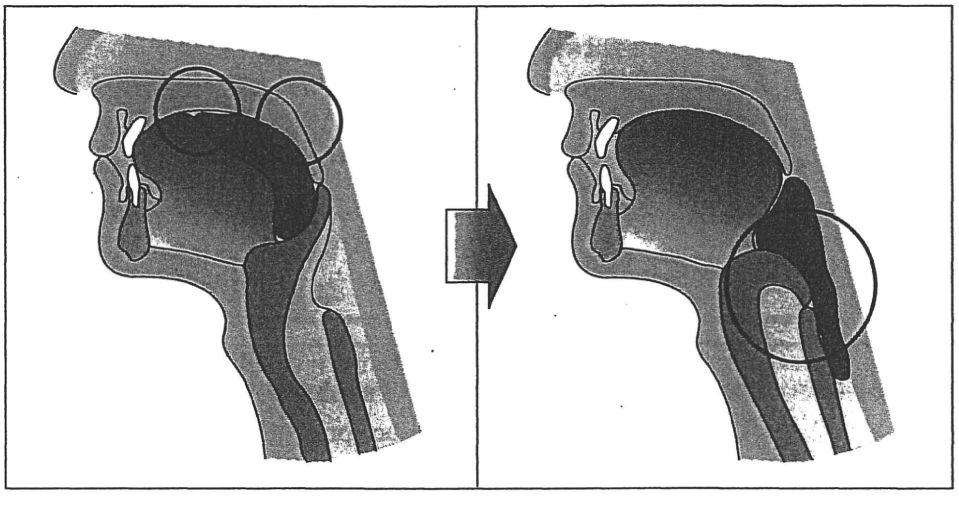

Figure 1.7 Bolus in pharyngeal phase

continuation swallowing. A feeling of residues may be based not only on what is depended on motility disturbance but on decrease of saliva secretion, and it will change with oral condition. When there is much residual volume, a risk of aspiration becomes high.

d) Esophageal Phase

Sympathetic nerve from upper cervical ganglion keeps UES closed except the time of swallowing. The stimulus of parasympathetic system carries out relaxation and opening of the UES at the time of belch, of nausea, and of swallowing. Furthermore, three mechanisms are associated in the opening of UES; UES relaxation accompanying pharynx contraction, mechanical opening by hyoid elevation, positive pressure which pushes out bolus to esophagus. Bolus size regulates the opening mechanism of UES. If bolus is large, nervous activity of UES at the time of swallowing will be activated at an early stage, and opening time will also be prolonged.

When bolus goes into esophagus, a peristalsis is generated from oral side to stomach side. The first wriggle wave is the largest, and the strength of a wriggle is influenced by the residual substance and clearance of pharynx. A wriggle will also become strong if pharyngeal clearance is good. Operation of the same bolus under multiple swallow inhibits a wriggle. The 2nd wriggle wave occurs in relation to spread of bolus in the esophagus. This 2nd wriggle wave sends the signal of LES opening. Although the bolus transfer of an esophagus varies with the texture, it takes 3 to 10 seconds.

3) Critical Points for Swallowing Movement

a) Blockade of Airway (Table 1.4, Table 1.5)

Velum palatinum is raised, and an upper airway is closed by being pushed against the posterior pharyngeal wall. Furthermore, hyoid and larynx elevate with contraction of base of oral cavity, and larynx approaches to epiglottis. Epiglottis is pushed by tongue base and sinks, and laryngeal aperture is closed. Closing of vocal cord and the stop of breathing take place simultaneously. A lower airway is intercepted by the above mechanism.

Table 1.4 Mechanism of airway protection

Lower airway closure	Vocal cord and vocal fold close.
Elevation of larynx	Larynx elevates below tongue base and tilts behind tongue.
Contraction of tongue base	Tongue is retracted backward, and bolus move away from the airway.
Epiglottis	Epiglottis is retracted by thyrolaryngeal tendon and turns over vestibule.
Vallecula	Bolus move in two way around the entrance of vestibule.
Swallowing apnea	Respiratory movements stops during swallowing.

Table 1.5 Organs with valve function for swallowing

Lips	make positive pressure in oral cavity
Soft palate	prevent flow to nasopharynx
Vocal cord	protect lower airway
Ventricular fold	protect lower airway
Upper esophageal sphincter (UES)	prevent reflux from esophagus
Lower esophageal sphincter (LES)	prevent reflux from stomach

b) Transfer of Bolus

The pharynx which was pressed and pulled in the transverse direction will spread in the front upper part, when the larynx carries out on elevation. Tongue moves by styloglossus and hyoglossal muscles, presses and pushes bolus, and proceeds it to the pharynx via isthmus of fauces. Although most of the bolus pass through piriform fossa, part of the bolus passes over epiglottis. Pharyngeal wall becomes shortened by lower constrictor muscle of pharynx, constrictor muscle above the bolus contracts, and bolus passed through entrance to esophagus. It is transported by the ring-like peristalsis.

In normal swallowing, the prompt transfer of bolus from mouth to stomach is possible. Liquid bolus passes pharynx within 2 seconds, and reaches to stomach in about 5 seconds. Transfer of the bolus is based on the motion by the muscle contraction and the gravity. Muscle contraction makes the portions of negative and positive pressure, and makes bolus transfer efficiently. This serial pressure formation is efficiently formed with lips, velum, vocal cords, and UES/LES at the time of swallowing (Figure 1.6, 1.7). A tongue forms the first positive pressure. Movement of tongue to lower back causes the elevation of larynx and hyoid bone. The elevation

of larynx makes negative pressure in pharynx, and transports bolus from positive pressure to negative one safely. It is abnormal that bolus moves to a portion which is originally in positive pressure and results in penetration and aspiration.

D) Examination for Dysphagia: Evalvation System for Aspiration Risk

HAZOP analysis is performed to find out all the risks comprehensively (by Guidewords and Deviation) and to take measures (Layers of Protection) in each process of swallowing movement. In this section, an outline is summarized about the method of inspecting as a detection system for dysphagia.

1) VFSS and FEES (fiberoptic endoscopic evaluation of swallowing)

VFSS can evaluate bolus passage condition and can also observe motion of swallowing related organs. It cannot be overemphasized that VFSS is the gold standard for evaluating ingestion and swallow function, while it is also the fact that the VFSS result is not always in accordance with actual ingestion and swallowing condition. VFSS enables observation of not only the existence of aspiration but functional abnormalities of a swallowing related organs. Thus, the result of VFSS applies for deciding rehabilitation methods, route of feeding, texture of food, and posture during swallow. Since VFSS can observe swallowing movements of each phase, abnormalities can be found easily.

In FEES the abnormalities of larynx and pharynx, the existence of residue, and vocal cord function can be seen directly under accepting reality on real time, although the moment of swallowing cannot be seen (white out). The greatest advantage of FEES is its portability, and it can use at bedside. Since there is no radiation contamination as side effects, examination can be performed repeatedly. However, sufficient cautions are required for nasal bleeding and vasovagal reflex (syncope). FEES incorporated with sensory-function testing (FEESST: fiberoptic endoscopic evaluation of swallowing with sensory testing) is also reported.

The significant correlation between VFSS and FEES is reported for pharyngeal residue (80% to 92%), aspiration (84% to 100%), and penetration (85% to 86%). In addition to two kinds of this standard examination, combination of

electromyography, tongue pressure measurement, and swallowing pressure measurement is also reported.

2) VFSS and other examinations for dysphagia

There are a few standardized questionnaire forms as dysphagia screening method, and they are reported in a self-entry type, a care worker entry type, and a medical staff entry type. The questionnaire (modified Fujishima Questionnaire) which we are using in our hospital revealed a specific pattern with different neurological diseases. The ideal questionnaire needs following three points. First, items consists of easy questions for patients, families, care workers, and medical staff, and result should not be influenced by experience of evaluators. Next, questionnaire could apply directly to daily meal and rehabilitation, if it contains an item about concrete ingestion and swallowing scene. It is also possible to offer the data which can respond to patient's swallowing training, foods creation, meal scene in a ward, and rehabilitation by a speech therapist. Furthermore, it becomes reference for the family and the care worker to make a meal at home. The third point is that the feature and severity of dysphagia can be judged to some extent.

Swallowing function is evaluated by voice change, dysarthria, cough after swallow, dysphonia, laryngeal elevation, and condition of saliva at a bedside.

Furthermore, although the correlation with aspiration is not shown, abnormality in pharyngeal reflex (gag reflex) and decrease of sensation in pharynx and larynx are reported to correlate with dysphagia. Though RSST (repetitive saliva swallow testing) is simple methods at bedside, there are few reports for applying RSST in deglutition disorders. It is reported that RSST decrease with the stability of a jaw. Although there are various reports about WST (water swallow testing), the volume of water varies according to reports. DePippo reported that 3-oz WST correlates with coughing during or after swallowing and wet voice in comparison with VFSS. Moreover, in Timed Test of drinking 150ml water, which measures the time and the number of swallow, revealed that dysphagia is correlated with extension of swallowing time, cough, and dysphonia. Daniels analyzed laryngeal elevation, the character of voice, and a cough at the time of swallowing water of various quantity. When two or more in six items (dysphonia, dysarthria, decrease of spontaneous

cough, cough after swallowing, decrease of pharyngeal reflex, and voice change after swallowing) existed, abnormal findings were presupposed by VFSS.

About evaluation of aspiration, VFSS, FEES, swallowing pressure measurement, pulse oxymeter, and scintigraphy are reported to be practical. About the above-mentioned inspection, it is reported that swallowing in unnatural state may be seen under examination condition, and variation is in the reliability between persons (interobserver reliability) and the reliability in a person (intraobserver reliability). Moreover, there is also a report that significant difference does not come out in pulse oxymeter.

3) Evaluation of Central Control for Swallowing Movement

About the central-nerves mechanism of swallowing movement has yet to be uncovered, although the analysis is reported with fMRI, magnetoencephalography (MEG), or PET. Activated area associated with swallowing is reported in primary sensorimotor area, supplementary movement area (SMA), insula, operculum, parietal lobe, and temporal lobe. Furthermore, there is a report about the activity change under voluntary swallow (command swallow, volitional swallow) and reflex swallow (non-command swallow, natural swallow).

Functional brain imaging is classified into two methods; detecting an electrical activity of the neuron itself (MEG and EEG) or a change of cerebral blood flow accompanying neuronal activity (fMRI, PET, and fNIRS). The latter is based on the theory that the brain blood flow will increase in the region where the activity increases. Since change of the amount of blood is delayed to actual neuronal activity, the time resolution of fMRI is an order of a second. Because swallowing movement perform within 700ms, time resolution of MRI is relatively low. On the other hand, in MEG which can catch cerebral electric activity directly, analysis is possible at the time resolution of milli-second order.

Moreover, in our research the brain functional activities in swallowing movement can be measured by functional NIRS (near-infrared spectroscopy). The NIRS measurement by optical topography equipment is useful to the brain performance analysis of the ingestion and swallowing movement accompanied by operation which free posture can take. Our results indicate that brain activity is widely activated by

volitional swallowing compared to reflective swallowing, and that movement of tongue, and of pharynx was separable with the difference of NIRS signal strength, and these results are in line with the previous reports by fMRI in a supine position. About the result of the NIRS signal pattern at the time of ingestion and swallowing movement, the application to the evaluation of function of swallowing difficulty and rehabilitation is expected.

E) Risk Analysis by HAZOP

As surveyed in this chapter, swallowing movement is controlled by the complicated process, and the risk management is not easy, either. Then, we considered HAZOP analysis to be the optimal method as the risk-analysis technique of swallowing difficulty. Table 1.6 represents the correspondence of the example of application in dysphagia with HAZOP sheet. Refer to the medical treatment HAZOP of Chapter 2 and Chapter 4 for details. The fine management of HAZOP analysis is attained with an inquiry of a risk more detailed as it enforces with a view from pathophysiological side to actual clinical care.

Table 1.6 Definition of HAZOP terminology in dysphagia analysis

Node, Subnode	each swallowing phase and more detailed process
Guideword	possibility to happen (or not to happen)
Deviation	abnormality in swallowing movement
Effect	results such as aspiration and pneumonia
Cause	Cause or mechanism of each deglutition disorder
Classification of the frequency	frequency of each deglutition disorder
Risk classification	significance of each disorder
Classification of the effect	contents of the effect of each disorder
Who	medical staff who is responsibile to check
Safety measure	examination for checking disorder

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Chapter 2

Medical HAZOP

A) HAZOP (Hazard and Operability Study)

Although various check list systems are created for risk assessment in dysphagia, it is difficult to inquire rare or hidden risks. Hazard and Operability Study (HAZOP) is one of the risk management tools for evaluating risk source. HAZOP is the method that the Chemistry Industrial Association (CIA) in Britain first published officially as CIA HAZOP Study Guide in 1974. It is an inquiry system of risks and track records, which accumulated for 30 years of history. Nowadays, HAZOP is applied to various industrial fields.

In this chapter the feature of HAZOP as a technique of an inquiry of a risk and applications of HAZOP will be introduced.

Many conventional accidents have occurred in the situation where a change (a change of design, a change of a procedure, a change of directions, etc.) is not correctly managed with. The risk inquiry technique should be selected to manage a possible change.

From the view of causes and results, the feature of HAZOP system is to determine several deviations and to analyze the results which occur from combined causes (Table 2.1). Thus, HAZOP is a system-based analysis tool which can clarify rare

Table 2.1 Methods for risk assessment and cause/ result

Mehod	Cause	Result
Checklist	casue=checklist	check=result
Fault Tree Analysis (FTA)	multiple causes	one result
Failure Mode and Effect Analysis (FMEA)	one mode	multiple results
Hazard & Operability Study (HAZOP)	deviation with multiple causes	multiple results

causes and rear effects systematically. Checking the accident which occurred in the past can be also included.

1) Overview of HAZOP analysis

HAZOP analysis aims at identifying the hazard of a process and the problem on operation.

The basic concept of HAZOP analysis is to investigate deviated process from normal status under a designed condition. If deviation from the original designed process condition arises, a possibility that the problem and the accident on the operation will come out. When an analysis team evaluates the cause and its influence by HAZOP, a guideword and a process parameter are used. These guidewords and process parameters are compared and contrasted with the process parameter which applies and corresponds to the specific point and specific section of process, and the possibility of the gap from predetermined condition is identified. The greatest strength of HAZOP analysis is being able to produce creative and innovative ideas by the brainstorming by members with various career. For this reason, it is important to create circumstances where members can exchange opinions freely.

2) Preparation for HAZOP

Although data required for preparation of HAZOP varies with scale and complexity of an object plant, data required for a general target is referred to the Piping & Instrument Diagram (P&IDs), a flow sheet, a plant arrangement plan, an operations manuals, a logic control figure, a logic diagram, or a computer program. A plant manual and an operator manual may be needed depending on the case. It is demanded for data to be exact and to be comprehensive. In the case of the existing plant, P&IDs should be checked, be updated, and is in agreement with the present condition, and the correction after plant construction is described in the drawing.

In the case of the chemical plant, most information is indicated by P&IDs. But in analysis of a human factor, it becomes possible to determine easily in HAZOP to set the node with role of a person according to the Work Breakdown Structure (WBS). Creating WBS is critical to perform analysis of all manufacture processes and operating processes by HAZOP (Table 2.2).

Table 2.2 An example of WBS

Node No.	Main Work	Person	Subwork	Problems and incident cases	Points to be paid attention
Inspection-1	Work1	Operator	Preparation for inspection (describe contents with timeline)	List up the point that mistake would happen in preparation and collect incident cases.	Describe the point to investigate
			Inspection work (describe contents with timeline)	List up the point that mistake would happen in inspection and collect incident cases.	Describe the point to investigate
		Inspector	Assessment of inspection	Judgment of a failure below the standard of decision	Standard of decision

3) Organizing HAZOP team

Usually, HAZOP study is performed in a multidisciplinary team, and members are selected based on the knowledge and specialty about design, operation, inspection, maintenance, and safety control. These days, a member well versed in the regulation applied from a viewpoint of legal compliance may be needed. Usually, it may be considered as 4-to 7-person organization, and every member has to have knowledge sufficient to the predetermined operation conditions of a plant.

It is important that the team leader is also skilled in HAZOP technique. Team leader has a role that members could observe to practice HAZOP. Therefore, a team leader is usually equipped with communication skills to command the staff who is not his subordinate, and thus the leader should be a talented person who can also pay careful attention to a subtle point. A secretary is nominated in the team to record the contents in a meeting, and the document would circulate to members by the following meeting.

Probably, the team leader will be desirable to be the person without the close relation to the plant investigator. Sometimes a technical contribution should not be expected from a leader, although sufficient technical knowledge which leads study appropriately is preferable for a team leader. It is effective for a team leader with prior training on the HAZOP technique.