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Notice

The Asian Medical Journal (AMJ) has changed its name to the Japan Medical Association Journal (JMAJ) from the April 2001 issue. The AMJ has been in publication for more than 40 years since its first issue. Its goal has been to promote medicine and health care mainly in Asia. Relevant articles were selected mainly from the Journal of the JMA and translated into English. It has been an academic journal containing the latest information in the field of medicine.

In conjunction with the change in the name, the journal's cover has been revised. The content of the JMAJ will continue to contain the latest information in medicine and health care in Japan, but it will be disseminated to medical-related organizations throughout the world, in addition to Asia. It will also contain information on JMA's activities and its stance on health care policies in Japan. Please note that the first issue of the JMAJ is volume number Vol. 44, No. 4 and the numbering continues consecutively from the previous AMJ issue. The ISSN 0004-461X will also continue to be the same. In addition, we are no longer accepting contributions to the AMJ or the JMAJ.

JMAJ Editorial Office

Optic Neuritis —From Diagnosis to Optic Nerve Transplantation—

JMAJ 44(7): 291–298, 2001

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Abstract: Optic neuritis is a clinical syndrome resulting from inflammation, demyelination, or infection of the optic nerve. Among several developed diagnostic procedures, the visually evoked cortical potential (VECP) has become a good tool to prove the impairment of the optic nerve. PVECP later became known to be closely related with ophthalmic conditions. In the ophthalmological field, we reported the influence of pupillary size, accommodation power, refractive powers, eccentricity of stimulated retinal area, retinal luminance, contrast, wavelengths, spatial and temporal frequencies, stimulus field, etc. On the basis of our results, we developed a television display system in 1975 and applied it clinically. In the present study, we reviewed the medical records of a total of 272 cases of optic neuritis who came to our clinic between 1978 and 1999. In the diagnostic, therapeutic point of view in relation with the data of other countries, the study was important regarding the racial differences and recent conceptions of optic neuritis. The results showed that there were no racial difference in optic neuritis as had been thought. The development from optic neuritis to multiple sclerosis was not less than in Caucasian patients. Regarding steroid therapy, we found that the most effective method was sub-Tenon injection. We have been studying the reconstruction of the optic nerve in Wistar rats. We experimentally damaged the ganglion cells by causing ischemic retina with ligation of the ophthalmic artery and cutting the optic nerve just behind the eyeball. To prevent the apoptosis of ganglion cells, we injected various neurotrophic factors such as BDNF, GDNF, and HSP 27 into the vitreous. For effective injection of cDNA and HSP 27, electropolation was applied and the best condition for avoiding apoptosis was chosen. Further, in Mx-*c-fos* transgenic mice, we found that regeneration of ganglion cells was inhibited. Based on the rescue study of the ganglion cells, optic nerve transplantation was performed using an artificial graft in which cultured Schwann cells from the ischiatic nerve, BDNF, CNTF, insulin, and forskolin were compound and bridged to the superior colliculus. The results showed a regeneration rate of the optic nerve axon of 18%. This rate was much higher than in other reports.

Key words: Optic neuritis; Visually evoked cortical potentials; Artificial graft; Rescue of retinal ganglion cells; Optic nerve transplantation

This article is a revised English version of a paper originally published in the Journal of the Japan Medical Association (Vol. 125, No. 1, 2001, pages 53–57).

Introduction

Optic neuritis (ON) refers to the clinical condition resulting from inflammation, demyelination, and infection of the optic nerve. In 1884, Nettleship[1] presented 28 cases of ON in detail, and described the symptoms commonly observed in these cases. The clinical features summarized by him, presented below, have not changed today, despite the passage of 116 years since: ① unilateral acute or subacute decline in visual acuity associated with pain during eye movement, ② recovery within one month in most cases, ③ onset at the mean age of 35 years (18 to 61 years), ④ central scotoma, ⑤ alteration of color vision, and ⑥ almost no abnormal ophthalmoscopic findings in the early stages.

As of the year 2000, improved electrophysiological and imaging diagnostic methods are used for the diagnosis, and adrenocortical steroids (steroids) are used for treatment of the condition.

With respect to the etiology, instead of associations with syphilis and tuberculosis, multiple sclerosis (MS) has become a major cause.

Recently, we analyzed the data collected from 272 patients with ON at the Department of Ophthalmology of Chiba University to examine the clinical features, diagnostic methods, association with MS and steroid therapy in these cases, with the objective of identifying valuable information regarding the current status of ON in Japan. Moreover, animal experiments aimed at exploring the possibility of optic nerve transplantation for promoting regeneration and reconstruction of optic nerves deemed as being beyond recovery are reported.

Advances in and Current Status of Diagnostic Methods

1. Establishment of electrophysiological diagnostic methods

(1) **Pattern visually evoked cortical potentials**

Among the patients with ON who consulted the outpatient clinic at the ophthalmology of our hospital during the 22 years between January 1977 and June 1999, the pattern visually evoked cortical potentials (PVECP) could be chronologically recorded by the pattern generating stimulator[2] developed by us in 190 patients. The diagnostic value of this method is summarized as follows: ① The PVECP abnormality rate (prolonged peak latency and decreased amplitude ratio) was 100% in the developing stages and 87% in the recovery stage, and there were no differences between cases of ON associated with MS and other types of ON; ② the steady-state PVECP is more sensitive for detecting abnormality than the transient PVECP; ③ the PVECP (peak latency and amplitude ratio) is correlated with the visual acuity; ④ the PVECP (peak latency) is correlated with the size of the central visual field.

(2) **Pattern electroretinogram**

The source of the pattern electroretinogram (PERG) is believed to be ganglion cells. PERG was recordable even in cases in which no prolongation of the peak latency was observed and PVECP was not recordable.[3,4] In the light of these findings, the retinal ganglion cells are considered to be relatively well preserved in cases of ON.

2. Imaging diagnosis

(1) **Magnetic resonance imaging (MRI)**

It has been revealed that the lesion of demyelination within the white matter can be visualized with a probability of at least 80% in cases of MS, and the diagnosis of MS has thus become simple.

While various methods have been attempted to visualize the lesions of the optic nerves,[5–8] no quantitative methods have yet been developed. Recently, we determined the signal intensity in the developing stage in 26 cases with ON of unilateral onset in an attempt to quantitatively analyze the site of optic nerve abnormality in cases of ON. In coronal fat-suppressed T2-weighted images, the signal intensity of the optic nerves of both sides and the intracerebral white matter were determined in the same

Table 1 Clinical Features and Laboratory Findings in 272 Cases of Optic Neuritis —Comparison of adults and children

	Adults	Children
Number of cases	232 cases	40 cases
Male:Female	1:1.8	1:1.2
Initial onset bilateral:unilateral	1:6.0	1:1.2
Age	39.5 years	9.3 years
Pain associated with eye movement	41.4%	30.0%
Vision at onset	0.33	0.09
Minimum vision, lower than 0.1	57.5%	80.0%
Recovered vision, 1.0 or higher	59.2%	92.5%
Duration until recovery of the optimal vision	92.7 days	90.6 days
Central scotoma	57.6%	64.4%
Recovery of normal visual field	42.3%	77.1%
Normal optic disc	40.8%	28.3%
Swollen optic disc	44.9%	71.2%
Duration until optic disc pallor	118.7 days	94.3 days
MRI abnormality rate	85.0%	
VECP abnormality rate	100%	100%
MS transition rate	9.5%	30%

Table 2 Clinical Features of Optic Neuritis—Comparison with those reported by other facilities

	Ophthalmological Dept. Chiba Univ. (2000)	Miller *et al.*[9] (1988)	Isayama *et al.*[10] (1982)
Number of cases	272 cases	37 cases	84 cases
Male-female ratio	1:1.7	1:2.0	1:1.5
Age	35.0 years	30.8 years	33.7 years
Bilateral:Unilateral	1:4.1	1:4.3	1:1.2
Pain associated with eye movement	33.1%	88%	—
Minimum vision, lower than 0.1	49.5%	59%	71.3%
Recovered vision, 1.0 or higher	64.3%	86.6% (over 0.7)	78.7%
Normal visual field	5.2%	13%	0%
Central scotoma	58.7%	74%	82.8%
Normal optic disc	40.8%	—	47.5%
Swollen optic disc	49.8%	42%	52.5%
MRI abnormality rate	85%	84%	—
VECP abnormality rate	100%	100%	—
MS transition rate	12.5%	50%	8.3%

field, and compared by calculating its ratio to the intracerebral white matter signal intensity (%). Determinations were made at 5 sites in the posterior part of the eye. By this method, the abnormality in the optic nerve could be detected in 85% of ON cases.

Clinical Features of Optic Neuritis (ON)

The clinical features of optic neuritis (ON) in adults and children are compared in Table 1. It was determined that the rate of transition to MS was higher in children than in adults.

Comparison of the clinical features reported

Table 3 Clinical Features of Cases Showing Transition to MS

Mean age	24.5 years (3–61 years)
Male-female ratio	1:1.83 (12 cases:22 cases)
Unilateral:Bilateral	2.78:1 (25 unilateral cases, 9 bilateral cases)
Pain associated with eye movement	32.4% (11/34 cases)
Papillary findings	Normal 51.2% (22/43 eyes)
Minimal vision	Mean 0.16
Recovered vision	Mean 1.0
Visual field	Central scotoma 59.5% 822/37 eyes)
Recurrent rate	52.9% (18/34 cases)
Within 3 months	27.8% (5/18 cases)
Frequency of attacks	Mean 3.4 times
Follow-up period	Mean 72.4 months

in other facilities is shown in Table 2. According to the statistics of Miller *et al.*,[9] the percentage of cases exhibiting pain associated with eye movement in other facilities was 88%, about 2.6 times higher than the figure of 33.1% in our series. The transition rate to MS was 50% in Miller's group, which was about 4 times higher than 12.5% in our series. In our series, when the patients who occurred ON at different time-points on either side included, the transition rate reached 20.6%.

The clinical features of patients with ON who eventually developed MS are shown in Table 3. It has been generally believed that transition to MS is rare in Asian people, suggestive of racial differences.[11] However, in the present study, among the 272 patients treated at our facility, a large percentage of 20.6% developed multiple sclerosis, suggesting that there may be no racial differences. This information appears to be epidemiologically relevant.

Methods of Treatment

Among the 272 ON patients in our series, there were no differences in the extent of recovery of visual acuity and the rapidity of its recovery resulting from differences in the steroid doses. Therefore, ophthalmologists may need to reconsider the importance of local injection of steroids into the Tenon capsule which has less systemic side-effect.

Animal Experiments

1. Experimental demyelinating optic neuritis

A mixture of anti-galactocerebroside antibody and guinea pig complement was injected subdurally into the optic nerve of Wistar rats to induce demyelination[12] and the ERG and VECP pattern changes with the passage of time were monitored. While no chronological changes were observed in the ERG, prolongation of the latency in VECP was observed one week after the antibody injection, and improvement was noted 2 weeks after the injection. Histologically, demyelination alone was observed one week after the injection while the optic nerve fibers were preserved, and improvement was noted 2 weeks after the injection. Since the ERG pattern showed no change despite the prolongation of the latency in VECP, the latter appears attributable to demyelination.

2. Reconstruction of the optic nerve circuit

Since the optic nerves have highly differentiated functions and form a very complicated network, protection and regeneration of the optic nerves could become possible only when all of the following requirements are satisfied: Maintenance of ganglion cell survival; regeneration of optic nerve fibers, and re-establish-

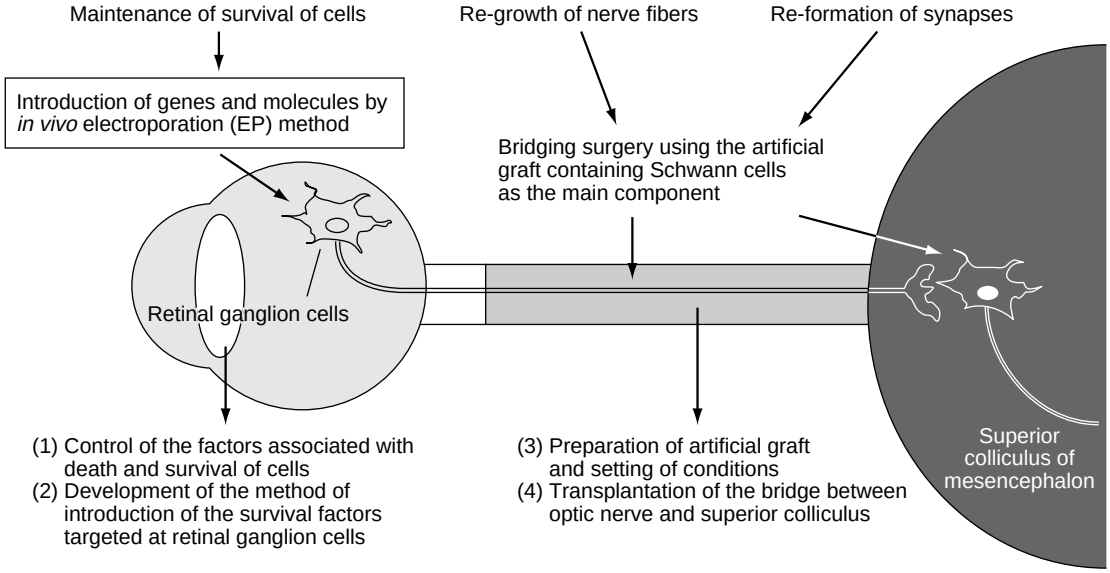

Fig. 1 Model chart of the experimental technique for optic nerve transplantation

ment of synapses in the central projection. Since all of these cannot be realized by any single means, a multi-angle strategy would appear to be necessary.

Our attempt is under way to maintain the survival of retinal ganglion cells by the introduction of genes or molecules to rescue the cells, and controlling the factors associated with cell death. Moreover, we are conducting research to accomplish regeneration of the optic nerve and establishment of synapses through development of artificial grafts and transplantation of the bridge to the superior colliculus (Fig. 1).

(1) **Maintenance of survival of retinal ganglion cells**

We employed two models of impairment of ganglion cells, i.e., complete resection of the optic nerve and temporal ligation of the optic artery to have ischemia-reperfusion. Mature rats were used as the experimental animals.

① Ganglion cell-protecting effects of heat shock protein (HSP27): HSP27 was injected into the vitreous body, and weak electric pulses were applied to facilitate the introduction. The number of surviving ganglion cells was significantly increased in these animals in comparison to that in the animals that did not receive any injection.

② Ganglion cell-protecting effects of the cDNA of brain-derived neurotrophic factors (BDNF): An optic nerve transection model was employed. In comparison to the number of ganglion cells noted in animals without transection of the optic nerve, about 90% of the cells died within 2 weeks after the transection of the optic nerve, and only about 10% of the cells remained viable. However, in the animals which received intravitreous injection of the cDNA of BDNF before transecting the optic nerve, cell death was dramatically suppressed, and the rescue rate increased to about 54.9%.

③ Regeneration of retinal ganglion cells and *c-fos*: The transcription factor, *c-fos*, is believed to be involved in the survival, regeneration, and death of nerve cells, but its precise role remains unknown. In the retina of *c-fos* knockout mice, apoptosis was scarcely observed. These findings suggest that *c-fos* plays an important role in apoptosis of retinal ganglion cells induced by damaged optic nerve.[13)]

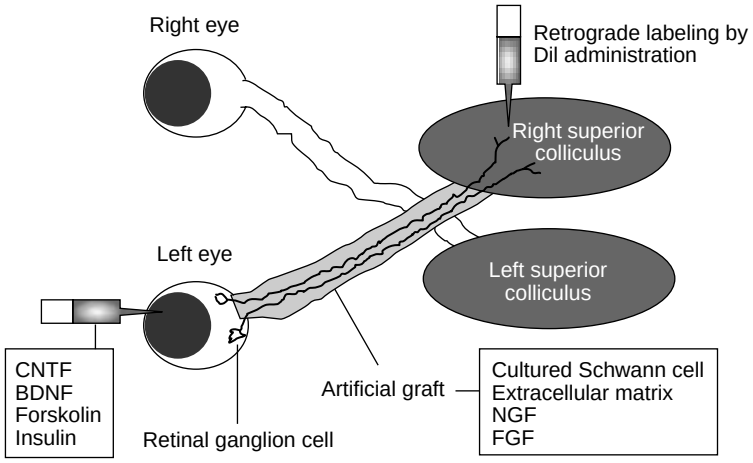

Fig. 2 Model chart of transplantation of the bridge to the superior colliculus using artificial grafts
DiI: One type of lipid-affinity carbocyanin fluorescence dye
CTNF: Ciliary neurotrophic factor
BDNF: Brain-derived neurotrophic factor
NGF: Nerve growth factor
FGF: Fibroblast growth factor

(2) **Optic nerve transplantation using artificial grafts**

It has been believed that degenerated optic nerves can never regenerate. On the other hand, peripheral nerves are known to possess the ability to regenerate and regain their functions after damage. The tissue surrounding the peripheral nerves consist mainly of Schwann cells, and the characteristics of these cells differ completely from those of the glial cells surrounding the optic nerve.

Accordingly, we attempted to artificially create an environment with a large density of Schwann cells to induce effective regeneration of optic nerves. We filled a silicon tube and a semipermeable tube with Schwann cells, extracellular matrix, and various neurotrophic factors, and transplanted them into the transected optic nerve as an artificial graft in an attempt to induce regeneration. The results suggested that it might be possible to induce regeneration of the optic nerve by creating an artificial environment using cultured Schwann cells, extracellular matrix, and neurotrophic factor.[14,15)]

Based on these results, we performed transplantation of the artificial graft to bridge to the superior colliculus, which is the central projection of the optic nerve in rats. In addition to Schwann cells and extracellular matrix, NGF and fibroblast growth factor (FGF) were injected into the graft to activate Schwann cells. Two months after the transplantation, retinal ganglion cells were retrogradely labeled with diI, and the regeneration rate of the optic nerve reaching the superior colliculus was found to be about 18%[16)] (Fig. 2).

Conclusion

This article has summarized the clinical data of optic neuritis collected by our department over the past 22 years, while reviewing the advances made in the techniques used for diagnosing optic neuritis. There has been no report based on the collection of a large amount of data from one facility such as this one before, and we have successfully determined the current status of optic neuritis in Japan. Since the results of our study revealed, unlike the concept suggested before, that there are no racial

differences in the causes of optic neuritis, we believe that our study has provided valuable data that may be relevant even in the global arena. Our results also showed a high incidence of progression from optic neuritis to MS, which is significant, because the conventional statistical data in Japan suggested a low incidence of transition to MS. In my view, more attention should be focused on research on the diagnostic techniques for MS in the field of ophthalmology, in addition to that in the field of neurology, and genetic diagnostic techniques not affected by racial differences should be introduced. It is a matter of regret that ophthalmologic studies on this topic are insufficient both in Japan as well as in Western countries.

Concerning the methods of treatment, local injection of adrenocortical steroids into the Tenon capsule has been suggested to yield favorable results. We experimentally attempted reconstruction of the optic nerve circuit by optic nerve transplantation using artificial transplants. As a result, introduction of neurotrophic genes and stress proteins, as well as regulation of expression of the transcription gene, *c-fos*, were revealed to be effective for maintaining the survival of retinal ganglion cells.

Our study also suggested that re-growth of damaged optic nerves can be induced by artificial transplantation of the optic nerve in an environment containing incubated Schwann cells as the chief constituent, and that regeneration up to the superior colliculus can be achieved in up to 18%. Thus, regeneration of the optic nerve can be induced by using artificial transplants under optimal conditions. The optic nerve circuit in humans may be unraveled in the near future. The possibility of successful transplantation in our study provides some hope for clinical application in the future.

The Journal of the Japanese Ophthalmological Society[17] should be contacted to obtain further details regarding the studies described in this article.

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Causes of Falls in the Elderly

JMAJ 44(7): 299–305, 2001

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Abstract: Falls are commonly encountered in daily life. Many of them are treated as accidents and are called accidental falls. Factors associated with repeated falling can be divided into intrinsic and extrinsic types, but several factors are usually involved in causing a fall. To identify the causes, the circumstance under which the fall occurred should be clarified in detail. Falls tend to occur when rising from and sitting in a chair, but also while walking on flat ground or a floor. Persons who are more likely to fall often have disabilities like hemiplegia, muscle weakness, parkinsonism, or ataxia, or else have cognitive impairment. Medications are another risk factor for falling. Particular caution must be exercised in patients who are taking hypnotics or tranquilizers. The majority of elderly persons fail to remember the details of a fall, so these should be clarified by information from members of the family or other witnesses. Although intrinsic factors must be treated to prevent the recurrence of falling, it is also important to examine and improve the living environment.

Key words: Accidental fall; Post-fall syndrome; House-bound; Rehabilitation

Introduction

Falls are common events in daily life and many of them can be considered accidental. The occurrence of falls increases in the elderly. Since Sheldon (1960) reported falls in the elderly,[1] many studies on the cause of these events have been performed. Current investigations on falls are based on the view that the factors predisposing to repeated falls can be divided into two categories, intrinsic and extrinsic, with multiple factors often being involved.[2]

What Are Falls?

A fall occurs when a person who is standing slips from an upright position and comes into contact with the ground. The person who falls may also contact the ground with a part of the body other than the feet instead of lying full-length on the ground. A fall onto the buttocks or knees can be also considered as a fall. These events are all regarded as falls in the International Classification of Disease (ICD) published by the WHO. There are two types of falls. One

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The Japanese text is a transcript of a lecture originally aired on August 24, 1999, by the Nihon Shortwave Broadcasting Co., Ltd., in its regular program “Special Course in Medicine”.

Table 1 International Classification of Falls (ICD-10)

Falls code	
W00	Fall on same level involving ice and snow
W01	Fall on same level from slipping, tripping and stumbling
W02	Fall involving ice-skates, skis, roller-skates or skateboards
W03	Other fall on same level due to collision with, or pushing by, another person
W04	Fall while being carried or supported by other persons
W05	Fall involving wheelchair
W06	Fall involving bed
W07	Fall involving chair
W08	Fall involving other furniture
W09	Fall involving playground equipment
W10	Fall on and from stairs and steps
W11	Fall on and from ladder
W12	Fall on and from scaffolding
W13	Fall from, out of or through building or structure
W14	Fall from tree
W15	Fall from cliff
W16	Diving or jumping into water causing injury other than drowning or submersion
W17	Other fall from one level to another
W18	Other fall on same level
W19	Unspecified fall
*Excludes: assault; fall (in) (out): animal, burning building, into fire, into water, machinery (in operation), transport vehicle; intentional self-harm	
Place of occurrence code	
. 0	Home
. 1	Residential institution: Children's home, dormitory, home for the sick, hospice, military camp, nursing home, old people's home, orphanage, etc.
. 2	School, other institution and public administrative area
. 3	Sports and athletic area
. 4	Street and highway
. 5	Trade and service area: Airport, bank, café, casino, garage (commercial), gas station, hotel, market, office building, petrol station, radio or television station, restaurant, shop (commercial), station (bus) (railway), store, supermarket, etc.
. 6	Industrial and construction area
. 7	Farm
. 8	Other specified places: Beach, campsite, canal, caravan site NOS, derelict house, desert, dock NOS, forest, harbour, hill, lake, marsh, military training ground, mountain, park pond or pool, prairie, railway line, river, sea, seashore, zoo, etc.
. 9	Unspecified place
Activity code	
. 0	While engaged in sports activity: Golf, jogging, riding, skiing, swimming, trekking, etc.
. 1	While engaged in leisure activity Excludes: Sports activities
. 2	While working for income
. 3	While engaged in other types of work: Domestic duties such as caring for children and relatives, cleaning, cooking, gardening, household maintenance
. 4	While resting, sleeping, eating or engaging in other vital activities
. 8	While engaged in other specified activities
. 9	During unspecified activity

Source: International Statistical Classification of Diseases and Related Health Problems. 10th Revision, WHO, 1992.

involves a series of movements in which the upper body descends from a standing position to the ground. In the other type, the whole body falls from one level to another. In Japanese, two different words "Tento" and "Rakka" are used to express these respective types of falls. Falls listed in ICD-10 for epidemiological studies include those from a bed or chair (Table 1).[3)]

Falls are not only one of the major causes of death in the elderly, but also result in a marked reduction of daily activities secondary to a decreased ability to walk or move and hence deterioration of the quality of life. Consequently, falls are recognized to be important internationally and are studied extensively.

Many falls are accidental. It has been reported that mortality is increased among elderly individuals who have fallen, even without a fracture occurring. Moreover, falls can lead to physical dysfunction, disability, and social disadvantage. The fear of falling again and the onset of unsteadiness when standing or walking can lead to confinement in a narrow sphere of living, where the elderly become largely inactive instead of continuing their former daily activities.

In the elderly, unexpected accidents such as falls are an important cause of death. Moreover, serious diseases such as myocardial infarction, pneumonia, and malignancy are often detected during hospitalization after a fall (premonitory fall).[4)]

In Japan, "bedridden elderly persons" remain a major medical and social problem. The greatest attention should be directed to falling, because it is one of the direct causes of elderly persons becoming bedridden.

To cope with falls, it is essential to clarify the characteristics of persons who have fallen previously and to identify risk factors. Persons who have fallen are defined variously in different studies. Epidemiological surveys on falls have usually been performed in persons who fell during the previous three, six, or twelve months. Falls are common events, except when complicated with a fracture or wound that requires prolonged treatment. In retrospective studies, the subjects may find it difficult to remember all of the falls that they have experienced. Consequently, the incidence of falls is likely to be underestimated. Accurate memories of falls by subjects are essential for retrospective surveys. To ensure accuracy, falls from standing are often defined as those in which the person lying on the ground or floor after falling must raise the body using the knees or buttocks to reach the upright position. In prospective studies, however, this problem is less serious. In some of them, particularly studies performed in Japan, falls leading to contact of part of the body other than the feet with the ground are also partly covered because of the difference in meaning between the English term "fall" and the Japanese counterpart. In Japan, a fall from one level to another is usually distinguished from a fall to the ground. In studies on post-fall syndrome[5)] and premonitory falls, falls are defined as events in which persons who have fallen need to move or need help to raise the body from the ground or floor regardless whether there are complications or not.[2)]

In many studies, about 30% of persons over the age of 65 who live in the community have been estimated to fall at least once a year. The incidence calculated at hospitals and institutions is difficult to compare because of the diversity of samples, which vary depending on the type of institutions and the circumstances under which hospitalization and discharge occur.

Risk Factors for Falls

Causes that make falls recurrent are summarized in Fig. 1. Because falling usually occurs unintentionally, it is called an accidental fall. Many causes usually combine to produce a fall. The causes can be divided into two categories, intrinsic and extrinsic. Intrinsic factors include disease and physical symptoms, whereas extrinsic factors are environmental. To identify the factors responsible for a fall, it is essential to define the circumstances under which the fall has occurred in detail by interview. A fall occurs when

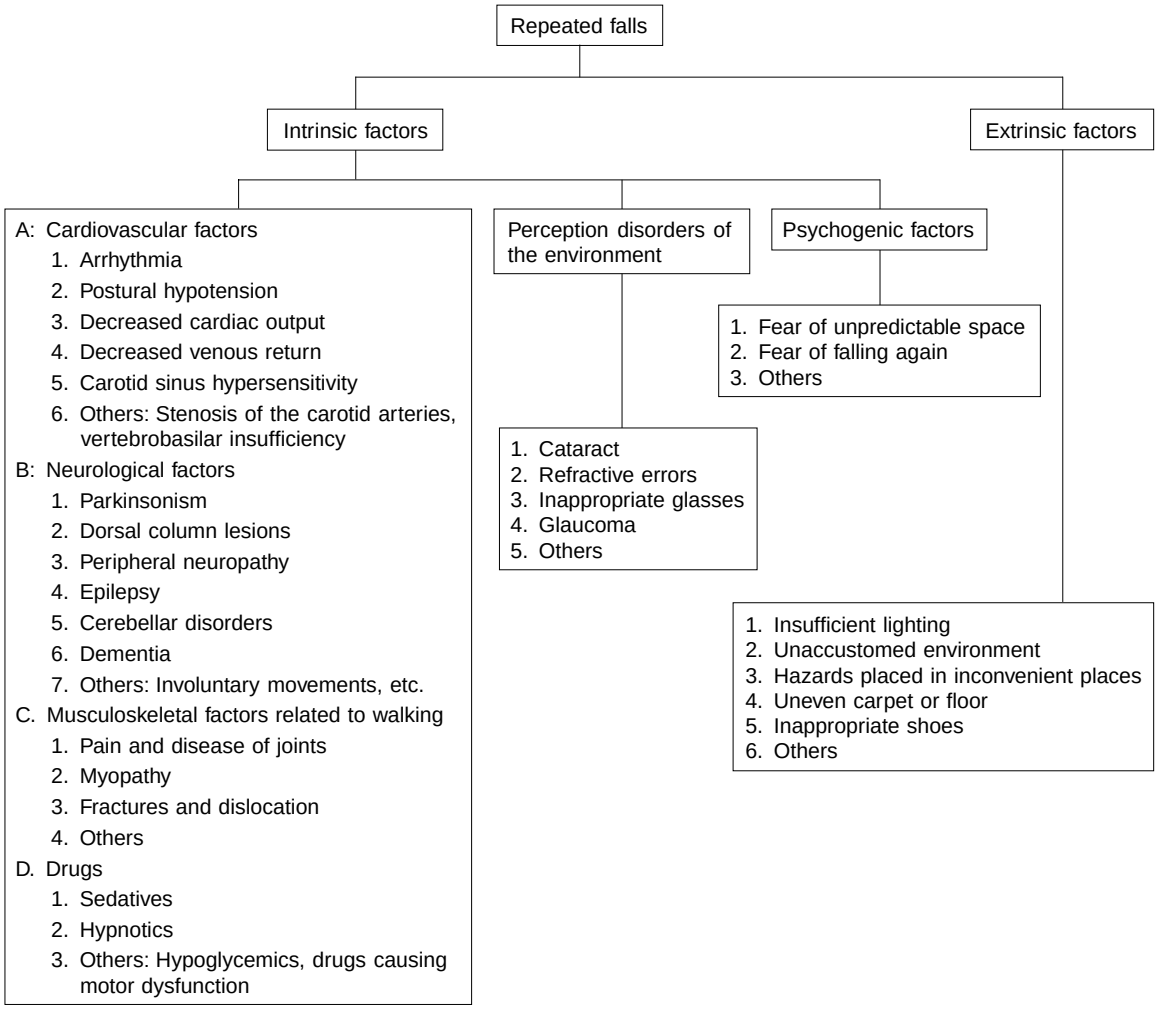

Fig. 1 Causes of repeated falls

a person moves and departs from the optimum position unexpectedly and fails to correct their posture by the righting reflex. The fall may be complicated by a fracture depending on the extent and nature of the defense reflex that is induced.

Situations in which falls may occur are as follows: 1) A fall may take place without external force while the victim is performing a usual movement, sitting in and arising from a chair or walking on flat ground, for example. 2) A fall may occur when an external force is exerted, for example, a gust of wind or an attack by a dog or cat. 3) A fall may occur when an individual encounters an unexpected hazard while performing an intended action, e.g., stepping on a banana skin or tripping while walking. Most falls fit into one of these three categories.

Type 1 falls result from inability to maintain the body upright or from severe abnormalities of balance. If such a fall occurs, neurological disease, disease of the musculoskeletal system related to walking, and drugs such as sedatives should be suspected. A sudden decrease in cardiac output or cerebral circulation due to postural hypotension and severe arrhythmias such as sick sinus syndrome may cause a fall as a result of syncope. Coughing, urination, or defecation may also cause syncope. The patient who has fallen often says, "Everything went

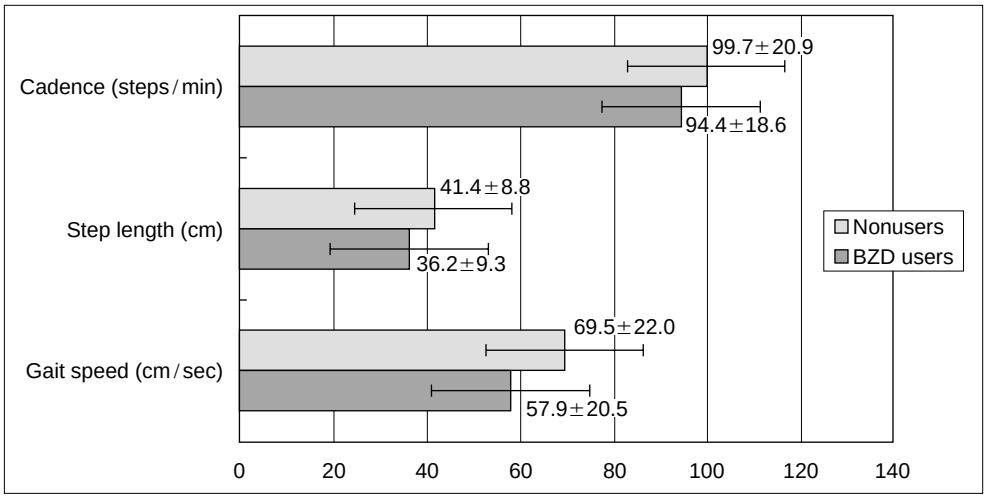

Fig. 2 Gait parameters in users and nonusers of benzodiazepines (expressed as the mean ± SD). The *p* values (*t*-test) are 0.344 for cadence, 0.040 for step length, and 0.054 for gait speed.

black suddenly" or "My head began to swim". Unlike falls due to abnormalities of balance, some falls may result from severe illness, so great caution must be exercised.

Type 2 falls occur when a person is surprised and changes posture too rapidly or is so disabled due to hemiplegia, parkinsonism, etc. that he cannot resist even a slight external force. Mild to moderate abnormalities of balance should be suspected. Individuals having severe aerophobia or a strong fear that they will fall again are likely to show an excessive postural response to a slight external force and so suffer a fall. This type of fall may occur in patients with post-fall syndrome, when their clinical course after the initial fall is poor. Care must be taken to prevent such falls.

In type 3 falls, the unexpected hazards are usually environmental, but the patients themselves may have cognitive impairment which makes them overlook hazards. The majority of elderly persons have some form of visual impairment, and they may miss hazards under certain environmental conditions. Impairment of visual cognition due to brain disorders is often associated with hemiplegia on the left side. Those who fall from bed may have an abnormal body sense or may be incapable of recognizing this abnormality. In young persons, falls of this type are usually attributed to mere absent-mindedness, but can be symptoms of a cognitive or attention-deficit disorder.

Medication is one of the intrinsic risk factors for falling. Particularly, hypnotics and tranquilizers are a significant problem because they can increase the risk of fractures due to falling. Regarding the association between falling and medication, the underlying disease for which the drug is being administered is more serious than the fall itself in some cases. Granek *et al.* performed an investigation about the association of falls with medications and disease in a long-term care facility for the elderly. They reported that drugs such as antidepressants, tranquilisers/hypnotics, vasodilators, and nonsteroidal antiinflammatory drugs (NSAIDs), as well as diseases such as osteoarthritis and depression were closely associated with falling. Overall, medication was more intimately associated with falls than disease. They also studied the influence of multiple drugs used in combination. The influence of three drugs or two drugs in combination was stronger than that of a single drug. The odds ratio was the highest for the combination of a diuretic, NSAID, and tranquilizer/hypnotic.[6] Benzodiazepines are com-

mon hypnotics. In elderly patients maintained on benzodiazepines or tranquilizers, the step length and gait speed are decreased, suggesting an increased risk of falling secondary to decreased walking ability (Fig. 2).[7]

The environment is an extrinsic factor that is more or less problematic in falls of any type. Many elderly persons who have fallen cannot remember the exact circumstances. Accordingly, the circumstances under which a fall has occurred should be precisely delineated with the help of family members or other witnesses. In many instances, multiple factors are involved in a fall.

Prediction of Falling

Many studies on the causes of falling have attempted to develop a system for risk management. Consequently, such studies are designed so that persons at high risk of falling can be identified and the system of preventing falls can be strengthened.

To predict falls, the association with 26 risk factors was assessed by analyzing the causes of falls occurring over three months in a 1,100-bed acute hospital in the United States. This study showed that only four factors were significantly associated with falling. The RISK tool, in which the four factors were incorporated, has been proposed to predict falls. The four factors are as follows: 1) Dizziness/unsteady gait/impairment of balance, 2) impairment of memory or judgement, 3) decreased muscle power (paralysis), and 4) a history of falling. In addition, the use of a wheel chair was considered to be a semi-risk factor.[8]

Among these factors, impairment of balance, impairment of memory and judgement, and decreased muscle power may be caused by the use of hypnotics or psychotropic drugs.

In hospitals or long-term care facilities, falls predominantly occur shortly after admission. Persons who are not accustomed to living in the facilities seem to be likely to fall. Among inpatients, 29.6% of all falls occur within 2 weeks after hospitalization, while the rate is reported as 46.5% by another study. According to a study performed in the rehabilitation ward of the Dokkyo University hospital, 42.9% (12/28) of falls occurred within one week after admission. Within two weeks, the rate increased to 53.6% (15/28). Thus, the risk of falling is high for around two weeks after the living environment is altered by a change of ward, hospitalization, or admission to a long-term care facility.

Conclusion (Prevention and treatment of falls)

In the treatment of persons who have fallen, priority must be given to the treatment of complications. It is rare for persons to be seen with the simple complaint of falling. In order to prevent falls which can make a person bed-ridden or house-bound in the future, the history of falling during the preceding three months should be obtained along with the causes. Various factors usually combine to cause a fall. In patients at high risk of falling, the intrinsic factors should be reviewed to improve balance and allow walking in an upright position.

Regarding extrinsic factors, it may be necessary to improve the safety of the living environment by wearing suitable shoes, installing rails, leveling floors, and improving the lighting. The color of walls or curtains may cause abnormal recognition in persons with impaired vision. Often, visual dysfunction can be corrected by cataract surgery or appropriate glasses. When there are central disorders of visual cognition, however, the environment must be improved to reduce the traumatic complications of falling. Small hazardous objects scattered over the floor can cause the elderly to trip and slip. Wet floors, e.g., as a result of urinary incontinence, are also slippery. Wet floors become more dangerous at night for persons who are going to the toilet because lighting is often insufficient. Studies on the causes of falling in the elderly have shown that pathological conditions and physical changes due to aging are combined. Thus, in order to protect the elderly from fall-

ing, not only diseases but also environmental factors should be taken into consideration.

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Prevention of Fractures Caused by Falls in Elderly Persons

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Abstract: Hip fracture usually occurs when the greater trochanter takes the impact of a fall. This was confirmed in our experimental study that simulated a fall onto the greater trochanter, since 75% of 24 femurs tested were fractured. Our experiment also showed that the fracture threshold for the hip of an elderly person was 2,166 N, while other researchers reported that the force exerted on the greater trochanter by the impact of a fall was 5,600 N. The large difference between these two values explains the high incidence of hip fractures in elderly individuals. To prevent such fractures, hip protectors were developed. We confirmed experimentally that a force-absorbing hip protector can reduce the impact force to 70%, and the load was further reduced to 54% when a force-dispersing device was added to it. A randomized clinical study was performed in 59 elderly persons living in nursing homes; no hip fractures occurred among the subjects wearing protectors, while four of the subjects without protectors suffered hip fractures. The incidence of hip fractures in the subjects not wearing protectors was higher than in those wearing protectors, although these two groups were equal to each other in terms of the frequency of falling, grip strength, thigh circumference, skinfold thickness in the upper arm, and ultrasonic bone assessment of the calcaneus. In conclusion, the hip protector is expected to prevent hip fractures in very elderly persons who have a higher risk of falling and decreased bone strength.

Key words: Hip fracture; Fall; Hip protector; Biomechanics; Osteoporosis

Introduction

In Japan, the orthopedic ward used to be full of patients with fractures caused by occupational and traffic accidents. Elderly patients with fracture of the spine or the hip were not noticed among the many other young patients. Because the elderly population has increased recently, however, orthopedic wards are now filled by elderly patients with fractures mostly caused by falls. Aging of the population will progress further in the future, so prevention of fractures caused by falls needs to be considered. We should not let the incidence of frac-

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tures rise unchecked.

We have been searching for methods to prevent fractures by falls, particularly hip fractures. The purpose of this article is to describe the preventive measures that have been devised and the results of our investigations.

Epidemiology of Hip Fractures

Hip fracture is a major problem because of its high prevalence and severity. Epidemiological studies performed in the United States have shown that falls account for more than 90% of hip fractures.[1] The treatment of this fracture was established long ago and many patients will recover the ability to walk if they can complete treatment uneventfully from operation to rehabilitation. According to Kitamura who performed a follow-up study of 1,169 patients in Japan, one year after injury, 67% of them had recovered the walking ability as before suffering the fracture.[2] However, walking ability was deteriorated in the remaining 33% and a considerable number of very elderly persons became bedridden. He also reported that the mortality rate was 6% at 120 days after fracture and then increased to 11% at one year. These results indicate that hip fracture is associated with a high mortality. Consequently, a reduction of the incidence of hip fracture is considered important because of the coming predominance of the elderly among the total population.

Mechanism of Hip Fractures

In order to prevent hip fractures, the mechanism needs to be elucidated, but it is not well-known. If a hip fracture occurs spontaneously, for example, while a person is walking or standing up from a sitting position, a fall will occur subsequently. Many orthopedists still think that hip fractures mostly occur in this manner. Although the fracture precedes a fall in some cases, they are exceptional, and the most common cause of hip fracture is secondary to a fall.

1. Site of impact

In brief, the majority of the hip fractures are produced when the great trochanter or the lateral aspect of the hip takes the impact of a fall. To investigate this mechanism, in collaboration with the Toyota Central R&D Labs., Inc., we developed a testing machine to simulate a fall onto the lateral aspect of the great trochanter. A fracture experiment was performed with this machine and 24 cadaver femurs. When a weight was dropped onto the greater trochanter, it produced a typical hip fracture in 75% of cases. This result showed that the femoral neck is fractured by an impact on the lateral aspect of the great trochanter.[3]

2. Magnitude of the impact force caused by a fall

The magnitude of the impact force on the greater trochanter during a fall has only been assessed in one experiment performed by Hayes *et al.*[4] This group raised young volunteers with the body in the lateral position up to a level of 70 cm above the ground and suddenly released them. The force exerted on the greater trochanter by the resulting fall was measured with a force plate. This showed that the force acting on the great trochanter in a fall was 5,600 N when the subject was in a state of muscle relaxation. Interestingly, this force increased to 8,600 N when the fall occurred with muscle contraction. In the present study, the lower value (5,600 N) was defined as the impact force.

3. Magnitude of the impact force that can cause the hip fracture in the elderly

According to another experiment performed by Hayes *et al.*, this force was reported to be 2,100 N.[5] In our fracture experiment,[3] the fracture threshold was 2,166 N, which is well consistent with the reported value, confirming the validity of our experiment. This indicates that, in elderly persons, the femoral neck is likely to be fractured by a force that is less than half of that exerted on the greater trochanter in a fall (5,600 N). This fact is noteworthy when attempt-

ing to establish preventive measures for such fractures.

4. Incidence of hip fractures caused by falls

Tinetti *et al.* studied 336 persons living in the community[6] and found that 108 fell during the one-year study period, with the incidence of hip fracture being 1%. This incidence is far lower than an estimate based on the difference between the impact force and the fracture threshold, as described above, which means that most elderly persons can avoid fracture in some way. Many factors may possibly be involved and precise knowledge of such factors could provide a key to preventing fractures caused by falls.

Factors Involved in Causing Hip Fractures after Falling

Factors that are presumed to influence the occurrence of fracture after falling include the ability to recognise the onset of a fall, the protective response of the upper extremities and trunk, attenuation of the impact on contact with the ground, and bone strength.

1. Recognition of a fall and protective response

If we notice that we are going to fall, we instinctively try to avoid it by holding onto something and taking a step forward, or we protect the head and trunk by breaking the fall with our arms and rotate the body to minimize damage. These events that occur before contact of the body with the ground still need to be studied further.

2. Bone strength

As described above, the force that can break the femoral neck in the elderly is much smaller than the force actually exerted on the hip in a fall. According to Courtney, the threshold load for femoral neck fractures at a mean age of 33 years was 7,200 N, indicating that persons of this age group are unlikely to sustain a hip fracture after a simple fall.[7] To prevent fractures solely on the basis of bone strength, it must be maintained at this level in the elderly, but this seems to be very difficult with current medical treatment. In other words, fractures cannot be prevented by only making efforts to maintain bone strength.

3. Reduction of the impact on contact with the ground

We have studied methods for attenuation of the impact force that causes hip fracture during a fall. Attenuation of the impact force by the floor covering is easy to understand. It is axiomatic that the severity of the injuries sustained in a fall varies widely depending on whether the floor is soft or hard. A fall on concrete, for example, may result in death or spinal cord injury, but the same fall on grass may cause no injury. Thus, the type of flooring often decides the outcome.

1) Soft tissue attenuation of the impact

The severity of the injury caused by a fall also depends on the properties of the soft tissues overlying the greater trochanter, which receives the impact. The physical properties of skin, fat, fascia, and muscle will vary with age, while a thicker layer of soft tissue has a greater ability to attenuate impact forces. An impact experiment carried out with human femurs and trochanteric soft tissues has actually demonstrated that thicker soft tissue absorbed more energy.[8]

2) Soft tissue in patients sustaining hip fractures

We performed a clinical study to compare 45 patients with hip fractures and 51 age- and sex-matched patients without fractures. This study showed that the total body amount of soft tissue, as assessed by dual-energy X-ray absorptiometry (DEXA), was 6.9 kg less (a significant decrease), in the patients with fracture than in those without fractures. In addition, there was a strong correlation between the total body amount of soft tissue and the thickness of the trochanteric soft tissues assessed by CT scanning. When these results are considered together, it

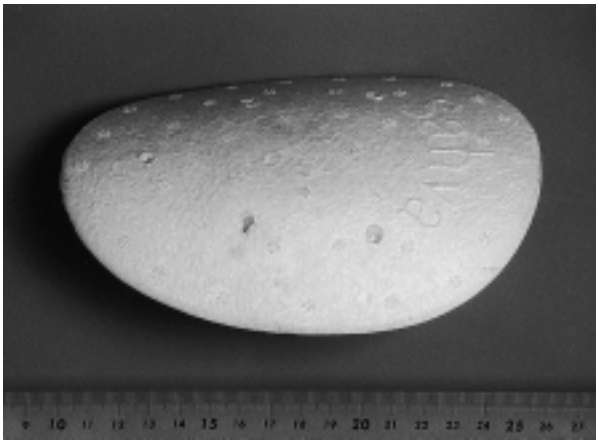

Fig. 1 Hard hip protector
This hip protector made of polypropylene is very light, weighing only 30 g. It is hard, but not uncomfortable because it closely fits the three-dimensional curvature of the greater trochanter.

Fig. 2 Hip protectors incorporated into an undergarment
Hip protectors have been sewn into underwear so that they cover the greater trochanters when the garment is worn and protect the hips. The protectors are detachable in some products.

seems that patients sustaining a hip fracture after falling have less trochanteric soft tissue and thus achieve less attenuation of the impact on the greater trochanter when they fall.[9] In other words, the soft tissue may act as a pad that protects the bone from fracture. A lean physique is considered to be one of the risk factors for hip fracture, and decreased attenuation of the impact force may partly account for this association.

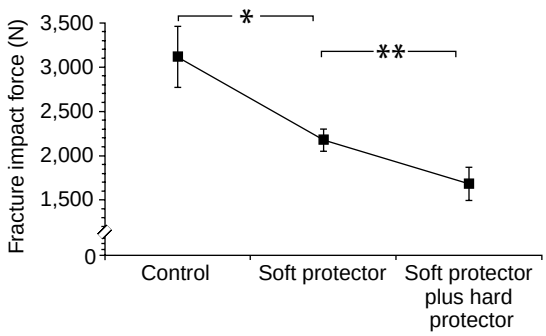

Fig. 3 Validation of effectiveness of hip protectors with an impact test[3]
Attenuation of the impact force on cadaver femurs was assessed using soft and hard hip protectors. The contralateral femur served as the control. *$p<0.01$, **$p<0.01$

Prevention of Fractures by Using Hip Protectors

1. Concept of the hip protectors

The idea of wearing a hip protector to prevent fractures seems reasonable when attention is directed to the role of the soft tissues in reducing the force exerted on the hip in a fall. In brief, a device that attenuates impact force could be placed over the greater trochanter to prevent hip fractures. This idea was investigated in Europe in the 1970s. In 1988, Worteberg actually used soft silicon pads as protectors in elderly persons.[10] Since then, hip protectors of various types have been developed in Europe and the United States. Virtually all of these protectors belong to either one of two types, which are helmet-shaped protectors made of hard materials such as polypropylene to disperse impact forces and protectors made of soft materials such as silicon gel to absorb impact forces (Fig. 1).[11] Most of these protectors are incorporated into an undergarment so that the greater trochanter is covered when the garment is worn (Fig. 2).

2. Pre-clinical evaluation of the effectiveness of hip protectors

Our weight-dropping experiment showed that

Table 1 Study on the Prevention of Hip Fractures with Hip Protectors in Nursing Homes[13]

	No hip fracture	Hip fracture
Hip protectors worn	30*	0
Hip protectors not worn	20	4

* Among the 35 elderly persons who wore protectors, five dropped out.
Fisher's exact test, $p = 0.0336$.

a soft silicon gel (force-absorbing) protector reduced the mean impact load on the greater trochanter from 3,117 N to 2,176 N (70%). When a hard (force-dispersing) protector made of resin was placed over the soft protector, the mean impact load was further reduced to 1,681 N (54%), a level below the hip fracture threshold in elderly persons (Fig. 3).[3] In other words, the use of a soft protector plus a hard one can reduce the impact load by more than 40%. Therefore, the use of hip protectors could result in a considerable reduction in the occurrence of fractures.

3. Clinical studies on hip protectors

1) Study by Lauritzen

In 1993, an 11-month follow-up study was performed in Danish nursing homes, with 247 and 418 elderly persons randomized to use or not use hard hip protectors, respectively. During follow-up, eight (3.2%) and 31 (7.4%) subjects sustained hip fracture among those wearing and not wearing hip protectors, respectively, with a significant difference between these two groups. Thus, the effectiveness of hip protectors was demonstrated.[12] In addition, all fractures in the hip protector group occurred while the subjects were not wearing their protectors. These results show that hip protectors can provide excellent mechanical protection of the hip, but that good compliance with wearing them is very important.

2) Studies in Japan

Only a few researchers have assessed hip protectors in Japan so far. Suzuki *et al.* performed a field survey to assess the wearing of hip protectors by elderly persons living in the community,[13] and they found that only 44% of the elderly subjects continued to wear hip protectors after 6 months.

We performed a study to evaluate the effectiveness of hard hip protectors for preventing hip fractures in nursing homes. Among the elderly women living in these nursing homes, 35 and 24 were randomized to use or not use hip protectors, respectively. They were followed for 19 months, while falls and fractures caused by falls were assessed. During the follow-up period, 64 falls occurred among the subjects wearing protectors and 32 falls occurred in the control group, and there was no significant difference in incidence between the two groups. No hip fracture occurred among those wearing protectors, but four women sustained fractures in the control group, and the hip fracture rate of the protector group was significantly lower than that of the control group (Fisher's exact test, $p = 0.0336$) (Table 1). In addition, analysis of data on factors related to the propensity to fall, the quantity of soft tissue, and the bone strength showed that these two groups did not differ significantly from each other in terms of grip strength, thigh circumference, skinfold thickness in the upper arm, or ultrasonic bone assessment of the calcaneus. Consequently, these two groups were equal in terms of their propensity to fall, soft tissue volume, and bone strength, so the results support the effectiveness of hip protectors for preventing hip fracture.[14]

Prevention of Fractures Caused by Falls: A Three-Pronged Approach

As described above, the use of hip protectors is a typical method of preventing fractures based on attenuation of the impact of a fall. This method is practical and may be highly beneficial for very elderly individuals at high risk of falling who also have decreased bone strength. Today, it is also possible to increase bone strength with drugs such as bisphosphonates. Because drug therapy takes years to sufficiently increase bone mass, however, it alone may be unsuitable for very elderly persons who are already at high risk. By wearing hip protectors, they can immediately protect themselves against hip fractures, so protectors are also useful from the viewpoint of instant protection.

Finally, I would like to emphasise that the maintenance of bone mass and prevention of falls are the basis of preventing fractures. For the prevention of hip fractures, elderly persons over the age of 80 years, around which time the incidence of hip fractures increases exponentially with age, should also use hip protectors in addition to these other two protective elements. It is very important to prevent fractures after falling by employing all three methods in a coordinated manner.

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Dysphagia in the Elderly

JMAJ 44(7): 312–317, 2001

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Abstract: Age-related neuromuscular dysfunction induces slowing of muscle movements. This is reflected in the swallowing process. Ingested bolus in the oral cavity may not be properly retained before the initiation of pharyngeal swallowing. Or the initiation of pharyngeal swallowing may be delayed, which often causes silent aspiration. The mortality of aspiration pneumonia is quite high in the elderly. Thus, oral hygiene is important for the prevention of silent aspiration. Cranial image findings often reveal cerebrovascular disease such as microinfarctions in elderly persons complaining of aspiration. Swallowing performance greatly varies in elderly persons. Biological age, not calendar age, should be considered in the diagnosis of elderly persons. Since the prevalence of dysphasia has been increasing with the surge of aging population, the etiology of dysphagia should be confirmed for proper treatment in individual patients.

Key words: Elderly population; Pharyngeal swallowing; Neuromuscular disorder; Aspiration

Introduction

Swallowing is a complex process that requires the coordinated actions of a large number of muscles and nerves. Pharyngeal swallowing (the transport of food from the pharynx to the esophagus) involves the swallowing reflex controlled by the deglutition center in the medulla oblongata. Thus, difficulty in swallowing in the elderly is often attributable to age-related central or peripheral nervous system impairment, or neurological damage associated with cerebrovascular or degenerative neuromuscular disease, which are common in the elderly.

Decline in physiological functions is generally observed in people over the age of 65 years. While the etiopathogenesis of dysphagia in young adults and the elderly cannot be clearly distinguished, close examination more often reveals organic disorders, such as mild cerebrovascular or degenerative neuromuscular disease, in elderly persons complaining of swallowing difficulty. The conditions may be asymptomatic, but they are frequently the cause of dysphagia.

Many elderly persons presenting with dysphagia are unaware of aspiration. When silent aspiration, often associated with vascular lesions in the basal ganglia, occurs repeatedly during

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sleeping, aspiration pneumonia may develop.[1)]

This paper describes the pathogenesis of pharyngeal dysphagia in the elderly.

Age-related Changes in Swallowing Functions

1. Mechanism of peripheral receptors[2,3)]

The propulsion of food into the pharynx stimulates the pharynx or pharyngeal mucosa, which in turn triggers the swallowing reflex. The pharyngeal mucosa contains numerous sensory nerve endings of the glossopharyngeal nerve and internal branch of the superior laryngeal nerve, in the form of free-nerve endings, beaded-nerve endings, and taste-bud structures. Although these nerve endings are believed to be concentrated in the posterior pharyngeal wall, our previous studies showed a wide distribution of the nerve-endings throughout the pharyngeal mucosa, with little variation in the density.

Around the larynx, many free-nerve endings of sensory nerves are noted in the epiglottis. There are a number of nerve endings running longitudinally along the mucosal propria layer at the base of the laryngeal surface of the larynx; myelinated nerve bundles are also observed in the deeper layers of the mucosa. Immediately under the epithelium lies a distinctive nerve plexus formed of beaded nerve endings, and branch, probably originating from sensory nerves, in the form of free-nerve endings, reside in the subepithelium.

A schematic depiction of peripheral receptors involved in the swallowing reflex is seen in Fig. 1. Such an elaborate structural network enables stimuli from a large area of the mucosa to be transmitted to the medulla oblongata. Although it has not yet been clarified as to whether all these nerve-endings are involved in the swallowing reflex, they apparently have functions as peripheral receptors for many protective reflexes, including the swallowing reflex. These nerve endings, slightly varying in their threshold for stimuli according to their location, are responsive to mechanical and chemical stimuli.

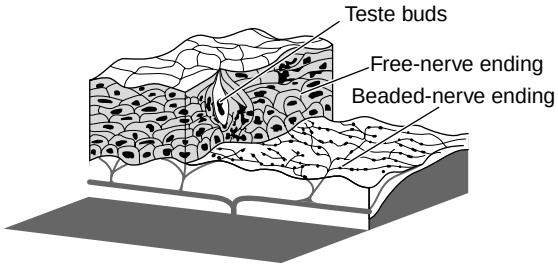

Fig. 1 Running of sensory nerve fibers and the distribution of their nerve endings in the laryngeal mucosa

How these peripheral receptors change with age still remains in the realm of speculation. Poor receptor response resulting from neurodegenerative disease or atrophy has been reported to lead to a decrease in the nerve conduction velocity.[4)] General degenerative changes in the nervous system may also affect the peripheral receptors. Furthermore, histological changes with age, including epithelial hypertrophy, metaplasia, and proliferative changes in the connective tissue, may also contribute to nerve receptor dysfunction in old age. Depressed pharyngeal reflex actions often cause slowing of swallowing in the elderly.

We have often encountered elderly patients with reduced pharyngeal reflex and its associated slowing of swallowing movements in clinical settings.

2. Role of the deglutition center[2,3)]

1) Sensory input from peripheral nerves

Peripheral sensory information is transmitted through the internal branch of the superior laryngeal nerve and the glossopharyngeal nerve to the solitary nucleus in the medulla. The binding site of synapse was partially projected into the medial and ventrolateral subnuclei, mainly the interstitial solitary subnucleus, and inputted for the formation of the subsequent swallowing reflex pattern. Furthermore, this sensory information is transmitted bilaterally through more synapses to the deglutition center in the

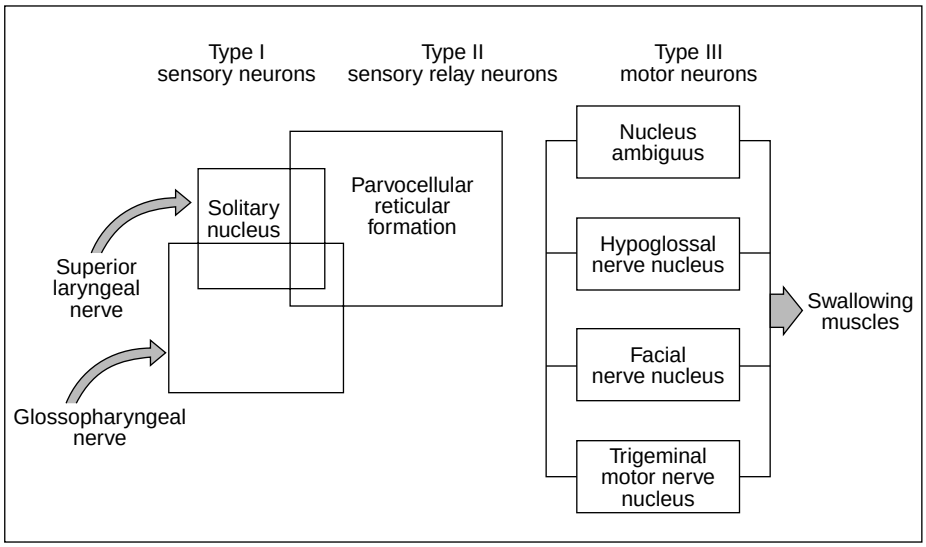

Fig. 2 Composition of swallowing-related neurons (medulla)

cerebral cortex.

2) Mechanism underlying the formation of the swallowing reflex pattern in the medulla oblongata

The formation of a swallowing reflex pattern in the medulla involves swallowing-related neurons in the solitary nucleus, reticular formation, nucleus ambiguus, and the hypoglossal nerve nucleus.

Although the involvement of two neuron groups, one located in the solitary nucleus and its adjacent reticular formation (the dorsal group) and the other in the nucleus ambiguus and its adjacent reticular formation (the ventral group), is known, we classified swallowing-related neurons in the medulla into three categories to elucidate the mechanism of deglutition based on their function and location: Type I (sensory neurons), Type II (sensory relay neurons), and Type III (motor neurons) (Fig. 2).[3)]

Type I neurons receive monosynaptic input from the superior laryngeal nerve and glossopharyngeal nerve, mostly in the interstitial solitary subnucleus of the solitary nucleus. At this stage, peripheral sensory information is integrated and conveyed to Type II neurons in the parvocellular reticular formation.

Type II neurons are interneurons that receive polysynaptic input from the sensory nerves. From these interneurons, information is further transmitted to Type III motor neuron nuclei, in which a swallowing pattern is generated. Type III neurons are motor neurons in the nucleus ambiguus and hypoglossal nerve nuclei, which drive the swallowing muscles to trigger a rapid sequence of the swallowing reflex in the pharyngeal stage of swallowing.

3) Control of swallowing and respiration

A series of protective reflexes inhibit respiration during swallowing. The laryngeal cavity closes to prevent entry of an ingested bolus into the airway. When this protective system fails, aspiration occurs. Respiration is also controlled during the swallowing process.

Swallowing is associated with a specific pattern of movement of the intrinsic and external laryngeal muscles, suggesting that a proportion of respiratory neurons recruited to the formation of the swallowing pattern may work to control respiration by linkage with the diaphragm and intercostal muscles. Such coordination may lower the subglottic pressure and facilitate the entry of an ingested bolus into the esophagus.

4) Role of the deglutition center in the cerebral cortex

It remains a challenge to identify the higher centers in the cerebral cortex in humans that regulate swallowing. Animal experiments have not been successful in clearly distinguishing between the deglutition center and the mastication center. There are still many issues that remain to be elucidated regarding the functions of the deglutition center.

We defined the area that the Type II neuron group directly projects on to in the cerebral cortex as the cortical deglutition area. The cortical deglutition area, which is observed bilaterally in the fronto-orbital gyrus, may exert promotive or inhibitory effects on the sequence of the swallowing reflex triggered by stimulation of the pharyngeal receptors.

5) Influence of aging on the neural mechanism controlling the deglutition center

How age-related changes in the nervous system affect swallowing remains unknown. Since the number of neurons in persons over the age of 80 years is believed to be decreased to 37% of that in younger adults, it is possible that impairment resulting from the decrease in the number of neurons may affect the mechanism of the central nervous system regulating swallowing functions.[5)]

3. Functions of peripheral effectors (swallowing muscles)

The numerous muscles involved in swallowing act in a specific coordinated pattern. During the swallowing process, the glottis closes as a result of sphincteric contraction of the intrinsic laryngeal muscle. At the same time, the pressures in the subglottic and interpleural regions also change.

Among the suprahyoid and inferiorhyoid muscles, the mylohyoid, geniohyoid and thyrohyoid muscles surrounding the larynx work in conjunction with the elevation of the larynx.

Among the pharyngeal constrictor muscles around the larynx, the hyo or middle pharyngeal constrictor muscle begins to contract in association with elevation of the larynx. Immediately thereafter, the thyropharyngeal muscle begins to contract. Subsequently, the descent of the larynx triggers activation of the cricopharyngeal muscle while the ingested bolus passes the pharyngo-esophageal junction.[5)]

The effects of aging on swallowing have been investigated using swallowing function tests. Radiographic studies have revealed that the position of the larynx during swallowing is relatively low in people over the age of 70 years, probably because of age-related decrease in muscular tone or deflection,[6)] which causes delayed laryngeal movement leading to aspiration. Such slight functional abnormalities and ill-timed movement may induce aspiration at the time of elevation of the larynx.[6,7)]

Swallowing efficiency varies in elderly persons. The epiglottis is sometimes found to tilt less during the swallowing process in people who have aspiration. Radiographic evaluation has revealed the presence of barium residue in the hypopharynx in persons over the age of 80 years, suggesting that peristaltoid movements of the pharynx become weak with age. Decreased efficiency of peristaltic contractions has also been reported to prolong the esophageal transit time of food in the elderly.[8)]

Dysphagia Observed Frequently in the Elderly

1. Causes of dysphagia in the elderly

Although there are no causes of dysphagia specific to the elderly, multiple cardiovascular or neurological disorders are significantly more frequently associated in the elderly. In particular, cerebrovascular disease, artherosclerosis, and hypertension resulting from degenerative disease induce functional impairment of the central nervous system (CNS). Dysphagia attributable to degenerative neuromuscular disease refers to the abnormal transport of an ingested bolus due to poor neural regulation of the swallowing process. The causes of dysphasia

Table 1 Classification of the Causes of Dysphagia Encountered Frequently in the Elderly

Dynamic disorder (disturbance due to abnormality of the transportation movement)
1. Corticobulbar tract disorders
Bilateral pyramidal disorders—pseudobulbar palsy
Extrapyramidal disorders—hypokinetic movement disorders, hyperkinetic movement disorders
Vascular disease: cerebral infarction, cerebral hemorrhage, etc.
Degenerative neuromuscular disease: amyotrophic lateral sclerosis, parkinsonism, Meige's syndrome
Poisoning: dyskinesia of the pharyngolarynx (mainly due to long-term treatment with antidepressants)
2. Brainstem disorders
Vascular disease: medullary infarction or hemorrhage, e.g., Wallenberg's syndrome (infarction of the region of the brain supplied by the posterior inferior cerebellar artery)
Degenerative neuromuscular disease: amyotrophic lateral sclerosis, spinal progressive muscular atrophy, etc.
3. Disorders of the peripheral nervous system
Inflammatory disease: Guillain-Barre syndrome
Metabolic disorders: diabetes mellitus, etc.
4. Neuromuscular junction disorders and myogenic disorder
Myasthenia gravis, muscular dystrophy

are classified in Table 1.[3)]

2. Pathology of dysphagia[9)]

1) Corticobulbar tract disorders

The features of dysphagia associated with these disorders vary according to the site of the lesion. Cerebral cortical disorders cause spastic paralysis due to impairment of corticobulbar or corticopyramidal tracts, as well as dyscoordination or dystonia of muscles resulting from extrapyramidal disorders. In this group of disorders, the dysphagia is generally mild. Careful attention should be paid in these patients, because many are unaware of their condition. Silent aspiration, if left untreated, could be life-threatening.

Bilateral corticobulbar disorders may cause pseudobulbar paralysis. This group of disorders is associated with delayed initiation of contraction of the impaired muscles and a slower transport of the ingested bolus into the pharynx. The swallowing reflex is triggered only with difficulty, but, once triggered, the muscles act to produce a normal swallowing pattern. Thus, the pharyngeal transit time of the bolus is not synchronized with the swallowing muscle movements, and a part of the bolus does not pass the pharyngoesophageal junction, and is left in the hypopharynx. This residue enters the airway through the larynx after the end of the pharyngeal swallowing.

Extrapyramidal disorders cause muscular dyscoordination or dystonia, leading to a variety of impairments such as hypokinesia and hyperkinesia. A typical example of this disorder is Parkinson's disease (PD). PD patients present with bradykinesia, but not many of them complain of swallowing difficulty. However, close examination reveals various types of mild swallowing impairment in these patients. PD affects the hypoglossal nerve nucleus, dorsal nucleus of the vagus, and the bulbar reticular formation, and the pathogenesis of dysphagia in these patients seems complex.

2) Brainstem disease

Brainstem disease is associated with impairment of the bulbar and spinal motor nerve nuclei, and is characterized by flaccid paralysis of muscles. Damage to the bulbar motor nuclei usually causes bulbar palsy associated with weakness or paralysis of the intrinsic and external laryngeal muscles. Dysphagia in patients with bulbar palsy is more severe than that in cases with pseudobulbar paralysis. Serious dys-

phagia is typically observed in patients with the lateral medullary syndrome, or Wallenberg's syndrome, associated with infarction of the brain region supplied by the posterior inferior cerebellar artery. Bilateral bulbar palsy also causes aphasia and aphonia. Swallowing difficulty in patients with unilateral bulbar palsy is characterized by impairment of oral stage and pharyngeal transfer of the ingested bolus. Incomplete pharyngeal transit of the bolus due to decreased swallowing pressure may cause aspiration.

3) Disorders of the peripheral nervous system

Disorders of the cranial nerves IX, X, XI, and XII cause swallowing dysfunction. In many cases, cranial polyneuritis develops after viral upper respiratory tract infection.

Isolated disease or combined disorder of the glossopharyngeal, vagal, and hypoglossal nerves is commonly associated with the development of dysphagia, but the prognosis is usually good.

4) Neuromuscular junction impairment and myogenic disorders

Diseases of the neuromuscular junction or the muscles *per se* include myasthenia gravis and muscular dystrophy. Paralytic or atrophic disorders of the muscles decrease the efficiency of muscular contraction and cause various swallowing disorders. Incomplete relaxation or contraction of the cricopharyngeal muscle severely obstructs the propulsion of an ingested bolus into the esophagus.

Conclusion

Age-related neuromuscular dysfunction induces slowing of muscle movements, which is also reflected in the swallowing process. An ingested bolus in the oral cavity may not be properly propelled before the initiation of pharyngeal swallowing; or the initiation of pharyngeal swallowing may be delayed, which often causes silent aspiration. The mortality of aspiration pneumonia is quite high in the elderly, and good oral hygiene must be ensured for the prevention of silent aspiration.

Cranial imaging often reveals the presence of cerebrovascular disease, such as microinfarctions, in elderly persons presenting with aspiration alone. The swallowing performance varies greatly among the elderly. The biological age, and not the calendar age, should be considered when examining elderly persons. Since the prevalence of dysphagia has increased with the surge in the aging population, the etiopathogenesis of dysphagia in the elderly must be clarified to ensure proper treatment of individual patients.

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Breast Cancer Screening with Mammography

JMAJ 44(7): 318–324, 2001

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Abstract: Breast cancer has been increasing in Japanese women. It ranks first in prevalence among female cancers, and it has been decided to include mammography in breast cancer screening examinations. The Ministry of Health and Welfare's notice "Policy for Health Education Stressing Cancer Prevention and the Conduct of Screening Examinations" emphasizes the importance of preparing an implementation system and of quality assurance of the equipment, images, and interpretation, and it directs that implementation be started in places where the system has been prepared. Mammography machines that fulfill the standards of the Japan Radiological Society and mammography that fulfills the image quality and imaging technology evaluation standards are required. Interpretation is performed twice, and the imaging technician and interpreting physician are required to have completed the training sessions conducted by the Mammography Screening Examination Quality Assurance Central Committee Education and Training Committee or similar training sessions. The goal of breast cancer screening examinations is to reduce breast cancer deaths, and the targets of the screening examinations that include mammography are women 50 years of age and over, in whom it has been demonstrated to be effective in the West. Since the peak incidence of breast cancer in Japanese women is in the 5th decade, the optimal approach to breast cancer screening examinations for women under 50 years of age is now being assessed.

Key words: Mammography; Breast cancer screening; Quality assurance; Cancer screening with mammography

Introduction

Breast cancer continues to increase in Japan, and the breast cancer incidence has finally become the highest in the country. Because the cure rate is high if detected early, and methods of early detection are available, screening examinations can be expected to be useful against breast cancer. Nevertheless, based on the results of studies that have shown that conventional inspection and palpation methods are inadequate and the results of examinations (including mammography) that are comparable to the West, screening that includes mammography has come to be performed since 1998 in Japan as well.

In this paper, the author reports on why mammography has been adopted and what is

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required for screening examinations that use mammography to yield good results.

Background behind the Introduction of Mammography

Breast cancer screening have been taken up by the 2nd Health Care Project for the Elderly since 1987, and screening examinations have been performed by inspection and palpation. Breast cancer screening by inspection and palpation were stated in the report of the Hisamichi Group (Study Group for Evaluation of the Efficacy of Cancer Screening)[1] funded by the Ministry of Health and Welfare in March 1998. "Despite the favorable 5-year survival rate for breast cancer detected on screening examinations compared to breast cancer detected in the outpatient clinic, no significant differences were found in the 10-year survival rates, and no mortality-reducing effect was shown." "A 45% mortality risk reduction effect was observed in persons who had not detected a lump themselves at the time of the screening examination." These statements showed the necessity of introducing examinations that allow breast cancer to be detected before patients feel a lump themselves.

Eight randomized controlled trials and 5 case-control studies on mammography have already been published in the West, and efficacy has been observed in its life-saving effect in the 50-year-old and over age range. Since the sensitivity, specificity, and early cancer ratios obtained in the Miyagi trial in Japan[2,3] were comparable to those reported in the West, where efficacy had already been demonstrated, screening examinations that include mammography were evaluated as having a high probability of being effective in Japan as well, and the conclusion was reached that "the introduction of mammography is indispensable to reliable reduction of breast cancer deaths by screening examinations" in Japan.

By contrast, although ultrasound examinations have received high evaluations clinically, the screening examination data were inadequate when used for primary screening. Therefore, they could not be used as material for assessment. In addition, there were many variations in the ultrasound examinations, including the equipment used, scanning methods, the persons performing the examinations, and the recording methods, and unfortunately, no recommended screening examination method or evaluation have yet been decided.

Policy of the Ministry of Health and Welfare's Policy in Conducting Screening Examinations That Include Mammography

Mammography was included in screening examinations for the first time in 2000. According to the "Policy for Health Education Stressing Cancer Prevention and the Conduct of Screening Examinations" dated March 31, 2000, "The target population of the introduction of mammography will be women 50 years of age and over, and an interview, inspection, palpation, and x-ray breast examination, consisting basically of medial and lateral oblique films of both breasts, will be conducted, and the films will be read twice in a suitable reading environment". What differs from the past is that the Ministry of Health and Welfare has directed that the mammography examinations "be started at sites where preparations have been made".

Especially in breast cancer screening examinations, since "when conducting breast cancer screening examinations, it is important to prepare a system for implementing screening examinations that includes quality assurance, etc." and "carrying out appropriate methods and quality assurance is essential, especially in regard to breast x-ray examinations", the quality assurance aspect has been emphasized in detail for the equipment, operators, readers, and quality assurance, in regard to implementation of the screening examinations and quality assurance by clear statements such as, the "Municipalities shall consider the relevant persons at public

health centers, local medical societies, contract provider institutions, etc., the implementation systems and implementation potential in the individual regions" and "the Breast Cancer Section of the Adult Disease Screening Examination and Guidance Council make arrangements with the relevant persons so that the screening examinations are performed smoothly, by appropriate methods, and under quality assurance".

The Ministry of Health and Welfare has mentioned quality assurance, because it has been demonstrated that adequate results cannot be expected when the quality of mammography is poor, even in mammography screening examinations of women 50 years of age and over, and it is important that Japan, which is a country that is behind in terms of instituting mammography examinations, not follow the same path.

Quality Assurance of Mammography Screening Examinations

Maintaining the precision of mammography screening examinations requires maintenance of the precision of the mammograms, the precision of the reading, and the precision of the system as a whole. This will be outlined below.

1. Quality assurance of mammograms

Mammograms are unique radiograms. Because the entire object being imaged is composed of soft tissue, special modifications are made so that even small differences in x-ray absorption between the soft tissue components create large differences in density on the x-ray films. Low-voltage x-rays having special properties are used. Ordinary x-ray tubes having molybdenum targets are basically used. Since image quality is altered considerably by even minor changes in voltage, machines having good voltage stability are essential, and molybdenum or rhodium filters must be used to reduce excessive "blurriness" or exposure.

Moreover, because of its shape, production of radiographs that enable observation of the interior of the breast requires machines and techniques that expand and compress the breast (mammary gland) so as to make it as thin and uniform as possible.

In addition, the screen film systems must possess the special high sensitivity and high contrast needed for mammograms. Therefore, development requires processing at a slower speed than usual radiography, and it is preferable that the intensifying screens and film systems be used exclusively for mammograms.

Evaluation of mammography equipment requires that 3 simulated mass points, 3 simulated calcification points, and 4 simulated fiber points be cleared on RMI-156-type breast phantom films and that image quality and technical evaluation be cleared in clinical cases. Detailed standards for the equipment and mammograms are described in the "Mammography guidelines" edited by the Japan Radiological Society / Japanese Society of Radiological Technology[5] and the "Quality assurance manual for breast cancer screening examinations by mammography" based on "Research related to promotion of breast cancer screening examinations by mammography and improving their precision", supported in part by the 1999 Health Care Project for the Elderly Fund.

To ensure quality assurance and the use of proper techniques, it is stipulated that it is preferable for mammography screening films to be taken by medical radiology technicians who have completed the training sessions held by the Education and Training Committee of the Central Committee on Quality Control for Mammographic Screening (composed of seven societies and groups related to the breast cancer care: the Japan Association of Breast Cancer Screening, Japanese Breast Cancer Society, Japan Radiology Society, Japanese Society of Radiological Technology, Japan Society of Obstetrics and Gynecology, Japanese Association of Medical Physics, and Japanese Association of Radiological Physics) or equivalent training sessions.

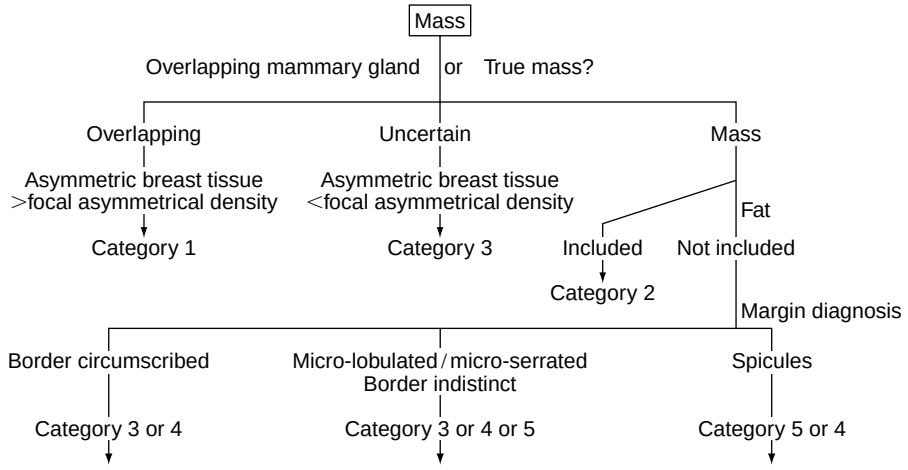
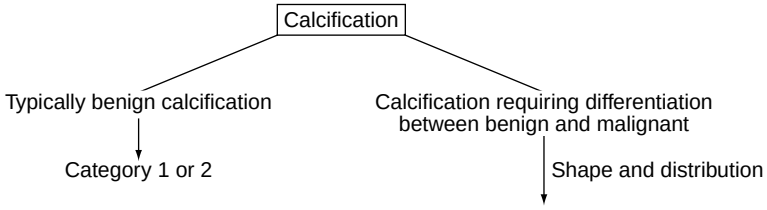


Fig. 1 Classification of masses



Distribution \ Shape	Small round calcification	Amorphous, or indistinct	Pleomorphic Heterogeneous	Fine linear Fine branching
Diffuse Regional	Category 2	Category 2	Category 3	Category 5
Clustered	Category 3	Category 3	Category 4	Category 5
Linear Segmental	Catgegory 3 or 4	Category 4	Category 5	Category 5

Fig. 2 Categorization of calcification

2. Quality assurance of mammogram interpretation

Mammograms are quite different from ordinary radiograms. First, the optical density of the film is greater than that of ordinary film (darker). Therefore, the amount of light provided by ordinary view boxes is insufficient, and interpretation of the films is impossible. Special mammography view boxes must be used, and preparation of the environment for interpretation is also important.

It is essential to interpret mammograms by using standard national terminology and evaluation criteria. They are described in detail in the "Mammography guidelines" mentioned above[5] and will be outlined below.

The special terminology (Lexicon) used to describe mammogram findings are explained by dividing them into terms for masses, calcification, and other findings. It is recommended that the evaluations be made by first clearly recording the degree of likelihood of being

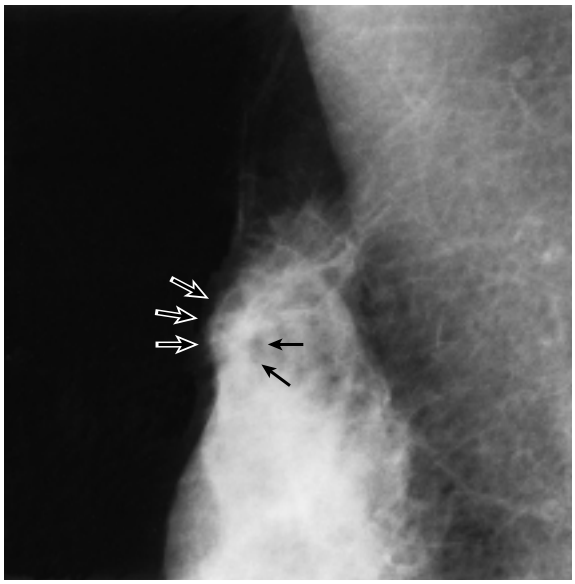


Fig. 3 A case of lobular cancer in which the mass shadow is concealed by the mammary gland and the architecture is distorted (dimpled / arrow)

benign or malignant by category, and then recording the histological diagnosis and the subsequent instructions.

When a mass has been found, its shape (round or oval, polygonal, lobulated, irregular), borders and margins (circumscribed, microlobulated / micro-serrated, associated with spicules, borders indistinct, obscured), and its density (low density, including fat density, equal density, high density). The borders and margins are especially important. Their use is also clearly prescribed in the form of a category decision tree (Fig. 1).

After first recognizing calcification that is typically benign and excluding it, calcification that needs to be differentiated according to whether it is benign or malignant is categorized according to its shape and distribution.

Typically benign calcification includes calcification of the skin, calcification of blood vessels, calcification associated with duct ectasia, solitary round calcifications, centrally radiolucent calcifications, milk of calcium calcification, calcification at suture sites, dystrophic calcification, etc. Calcification that requires differentiation between benign and malignant is divided, on the basis of shape, into fine round calcification, amorphous (or indistinct) calcification, pleomorphic or heterogeneous calcification, and fine linear or fine branching calcification, and on the basis of distribution, into diffuse / scattered, regional, segmental, linear, and clustered, and as shown in Fig. 2, it is categorized according to combinations of them.

The other findings have been organized into mammary gland parenchymal findings (tubular density / solitary dilated duct, asymmetric breast tissue, focal asymmetrical density, architectural distortion, trabecular thickening), cutaneous findings (skin lesions, skin thickening, skin retraction, nipple retraction), and lymph node findings (axillary adenopathy, intramammary lymph nodes).

One of these findings, architectural distortion, differs from the conventional concept of "mass plus calcification", which has been interpreted as mammographic evidence of breast cancer, and it is now possible to recognize abnormal findings by taking mammary gland architecture into consideration. In concrete terms, this means findings in which there is no clear mass shadow, and spicules radiating from a single point and a mass shadow are not present or cannot be seen, but there are such findings as the margin of the mammary gland parenchyma being locally indented, or the mammary gland parenchyma being warped (Fig. 3), and these findings should arouse suspicion of cancer in patients with no history of surgery or severe inflammation. Accurate interpretation of these findings must be based on proper imaging techniques and scrupulous methods of interpretation.

3. Quality assurance of the system

The conduct of screening examinations is currently the responsibility of local governments. It is stipulated in regard to the quality assurance of screening examinations that "the breast cancer sections of the adult disease screening examination and guidance councils

established in the prefectures shall make arrangements with the relevant members of the regional medical society, the contract provider institutions, the detailed testing institutions, etc., so that the screening examinations are carried out smoothly by appropriate methods and under quality assurance"; however, in concrete terms, it is necessary to maintain the accuracy of mammogram image quality and interpretation, to prepare records, and to provide guidance in understanding the results of definitive diagnosis and the circumstances of treatment, etc.

The institutional image evaluation committees of the Central Committee on Quality Control for Mammographic Screening mentioned above are expected to play a role in these quality assurance operations.[7)]

Radiation Exposure as a Result of Mammography

Although the radiation dose to the breast during mammography differs slightly according to the physique of the subject and according to the machine used, measurements have shown it to be approximately 1–3 milliGray (mGy; absorbed radiation dose). When this is converted to actual radiation dose, it amounts to 0.05–0.15 milliSieverts (mSv), and comparison with the definite-effect threshold value shows that they are one order of magnitude smaller and constitute no problem whatsoever. From the standpoint of probable effect as well, an increase in cancer incidence has only been demonstrated at several hundred mSv or more. They are truly an order of magnitude different and constitute no problem at all.[6)] In other words, as long as mammography screening examinations are carried out properly, there is no need to consider the negative effects of the radiation exposure.

Breast Cancer Screening Examinations of the Future

Breast cancer incidence is still continuing to increase, and it is impossible to lower breast cancer mortality by conventional examinations. Screening examinations in the future will be expected to decrease breast cancer deaths even if the rate of occurrence of breast cancer increases. Accordingly, it will be necessary, first, to implement high-precision screening examinations capable of detecting breast cancer before the occurrence of symptoms, such as a self-detected "lump", and, second, to increase the percentage of the population that undergoes breast cancer screening examinations.

While screening examinations that include mammography are currently being provided to women 50 years of age and over, the peak incidence of breast cancer in Japan is in the 5th decade, and breast cancer mortality peaks in the 6th decade. Thus, it is very important to rapidly design and implement breast cancer screening examinations that can decrease breast cancer mortality in women under 50. One of the groups supported by the Ministry of Health and Welfare Cancer Research Fund, the group conducting "Research on the optimal method of breast cancer screening examination for women under 50 years of age" is engaged in the collection of material from both mammography and ultrasound examinations, and results are expected very soon.

Conclusions

The background underlying the introduction of mammography and the importance of quality assurance are described on the occasion of the start of screening examinations including mammography in Japan.

It is very important that high-precision screening examinations be implemented in screening examinations that include mammography only after attending training sessions on the production and interpretation of mammograms, and a reduction in breast cancer deaths is expected as a result. In the future mammography may be applied to women under 50 years of age, and the concept of quality assurance will become increasingly important.

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Control and Prevention of Medical Malpractice

—Keynote Speech in the Seminar on Patient Safety—

JMAJ 44(7): 325–334, 2001

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Abstract: There have been a number of medical cases of malpractice at the Musashino Red Cross Hospital. In 1995, we established a "Medical Practice Evaluation Committee" consisting of 11 doctors to review incident reports submitted by doctors describing their mistakes to resolve their own problems with reference to risk management systems in the field of aviation. I discuss the challenges faced by the Musashino Red Cross Hospital in preventing medical malpractice by referring to the principle that improvement of the institutional operating system should be based on the principle that even a minor incident can become a lesson to be shared by the whole hospital. Also, I address the establishment of risk management system in a hospital and what the medical field can learn from the risk management system in the field of aviation.

Key words: Risk management in healthcare; Medical risk management; Healthcare risk management introduced from aviation risk management

There had been a number of cases of medical malpractice at Musashino Red Cross Hospital, and since the autumn of 1994 the hospital has been engaged in activities to prevent such malpractice. Today, I will begin with the history of this situation.

Next, I will describe approaches to the establishment of risk management systems from the perspective of both a health care institution and as an individual concerned with patient safety.

Lastly, I will point out what the medical world can learn from the field of aviation, a matter I have been studying.

Traditional Approaches to Medical Malpractice

In response to medical malpractice the traditional form of investigation focuses on what happened, who was responsible for it, and who had previously been responsible. Then the incident is eventually settled by punishing the responsible person. Most medical malpractice has

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been dealt with in this manner, in what is called the responsibility-oriented approach. It never improves the situation.

It is necessary to implement a cause-oriented approach, or to discuss causes and required measures in order to prevent such incidents.

Approaches to Preventing Medical Malpractice

Let me introduce a brief history of the situation at Musashino Red Cross Hospital. There have been a number of cases of medical malpractice at Musashino Red Cross Hospital. During the 5 years between 1988 and 1992 there were 5 major cases of medical malpractice. The hospital paid settlement packages of over 250 million yen, which involved payments of 7 to 20 times the insurance premium. The highest demand for compensation was 340 million yen, but it was finally reduced to 110 million yen.

I was appointed as a Vice-President of the hospital in 1992. In 1993, a manager of the insurance company through which the hospital was covered visited the president of the hospital. I met him in behalf of the president who was absent, and I became involved with the matter. Some of his comments impressed me greatly.

Let me illustrate an example. When a fire occurs in a factory, the company investigates its cause through various means. As a result, the company rarely repeats the same type of accident. In contrast, accidents of the same type repeatedly occur in the same hospital. He said, "Why does it happen? Is it impossible to learn from mistakes in medical care?" His words shook me and I thought I had to do something to improve the situation. In addition, the insurance company strongly requested the introduction of institutional preventive measures to prevent medical malpractice.

In the Musashino Red Cross Hospital, each department has its own way of medical practices. In a sense, however, an individual doctor starts a private practice in a hospital. As I thought that there was no institutional control system to establish the overall direction and level of health care in the hospital, I started to implement measures to prevent medical malpractice.

The first goal we set was to raise the awareness of medical malpractice among medical professionals.

We thought that the Quality Control (QC) activities, that have supported Japanese industries, were the most appropriate means for this purpose.

We asked a QC group in each work unit to select topics through a top-down approach, focusing on the prevention of medical malpractice. A total of 11 groups started QC activities. All QC group activities ceased after about 2 years because the top-down system was adopted instead of the preferable bottom-up system, and the majority of the topics covered by the QC activities concerned problems related to nurses alone. We are currently trying to resume QC activities with a bottom-up approach.

We learned a lot from the QC activities over these two years, and I believe that the experience established the basis for future activities to prevent medical malpractice in our institution.

The nursing section has traditionally been involved in efforts to prevent medical malpractice. In association with this new venture, they started to make various improvements including revision of their accident report forms. Within a period of 18 months, the nursing section developed a manual entitled "Accident Prevention." On completion of the manual, doctors were pressed to take action. But I could not respond to their concern.

In response, the doctors themselves decided to introduce an incident reporting system. We organized a "Medical Practice Evaluation Committee," that was later renamed the "Medical Risk Management Committee." It is composed of 11 doctors. I will give you the details later.

Then we tried to establish a risk prediction system. All of the department heads were asked to prepare a list of accidents that were most likely to occur in medical care in their departments and to formulate and submit measures

to prevent them. These reports have been incorporated into appropriate chapters of the "Manual to Prevent Medical Accidents."

Risk Management Technology in the Field of Aviation

At the beginning of our attempt to deal with medical malpractice, Dr. Isao Kuroda, then a professor at the School of Human Sciences of Waseda University, suggested the introduction of risk management technology developed in the field of aviation because malpractice in health care resembles the accidents that occur in aviation.

There is a well-known saying of "chain of events" in aviation accidents. Meaning that three or more minor incidents always occur in a row before a larger, more serious accident. This is called a chain of events. Every pilot is instructed to faithfully report every incident that occurs during a flight regardless of its seriousness (including near-miss incidents). They are assured that filing such reports will in no way affect their chances of promotion or future pay increases. This encourages honest reporting. Safety in aviation is ensured by compiling and analyzing these incident reports to cut the chain of events at an early stage.

Incident Reporting

We still use a registered incident/accident report form. It requires completion of the following sections: Diagnosis; place, date and time, type and conditions of the accident; subsequent reaction to the accident; evaluation of the degree of risk; mental and physical health status of the medical personnel involved; views on the cause of the accident; and thoughts on the steps to be taken in future. These are submitted to the general affairs section, and transferred to me.

However, there are some problems in the incident reporting system. One problem is whether a report will be registered or not. Because a registered report requires strict control, some specialists say that it should not be registered.

However, because of three consecutive incidents caused by the same doctor in the hospital, we do not discuss the registered system.

Another major problem is that the incident reporting system is not legally enforceable, which is closely related to the matter of registration. If it is expected that information will become available by some other route for other purposes, including legal affairs, reporting cannot be effectively implemented.

Therefore, I consider it necessary for the government to urgently provide legal protection for the incident reporting system. In Japan, it has been regarded as a kind of taboo to review the medical practices of doctors in investigating medical accidents. Accordingly, medical incidents that come into a gray zone of malpractice remain unresolved. This situation will decrease confidence of doctors as leaders of the team in medical practices. I believe that the objective evaluation of various problems in medical malpractice, even if they are minor, will be of benefit to the entire hospital.

Establishment and Responsibility of the Medical Practice Evaluation Committee[1–7)]

A properly functioning system with self-appraisal by doctors to resolve their own problems will reduce medical malpractice in a hospital. The Management Conference approved my proposal to organize a Medical Practice Evaluation Committee based on this concept. In order to obtain the consensus of the hospital staff, I explained the purpose at department head meetings and wrote an article for a internal hospital newsletter.

Later it was renamed the "Medical Risk Management Committee," and consists of 11 doctors from 11 departments, including 6 department heads and 5 assistant heads. The standard for selection was based on the capacity to provide experienced and balanced judgement. The committee meets once a month. Based on

the incident reports, this committee investigates various factors such as problems related to medical technology, appropriateness of clinical judgements, the working backgrounds, and the psychological condition of the medical staff.

It is most important to note that an incident seemingly caused by an individual mistake is sometimes the result of the hospital system itself. In this case, the system should be changed or revised. Also the monitoring functions within the hospital need to be reviewed.

Such a review sometimes discloses problems on the part of the patients.

It was also hoped that the committee would play the role of a medical audit system. At first the committee was going to hold CPC (clinicopathological conference) or inquiries related to deaths, but they have been restricted to prior hospital incidents due to various internal conditions. I think that as a result the committee has strengthened its function as a medical audit system.

Learning from Actual Cases

Let me introduce two malpractice incidents.

A 49-year-old patient with a pacemaker was carried into the emergency department after a tachycardia attack. The doctor in attendance ordered 50 mg of Xylocaine. Intravenous injection of the fluid in the provided syringe relieved the tachycardia, but made the patient unconscious with muscle cramps. The doctor did not realize what had happened, and moved the patient to the ICU where the patient was satisfactorily treated. The doctor found that the injection he had administered was an ampule containing 1,000 mg of Xylocaine, not 100 mg. His prescription had been for 50 mg of Xylocaine, but he actually administered 500 mg. This caused an acute Xylocaine adverse reaction in the patient.

Based on this experience, the Committee reorganized medicines in the emergency department. The committee discussed the necessity of providing 1,000 mg ampules of Xylocaine. Xylocaine in 1,000 mg ampules is usually used to prevent arrhythmia in medical drips in ICUs and CCUs, but it is rarely used in emergency departments. As the availability of 1,000 mg ampules of Xylocaine in wagons in the emergency department can result in mistakes, all of them were transferred from the wagon to a cabinet.

At the same time, the Committee investigated drug names that can easily be confused, in cooperation with the pharmacy. A list of these was distributed to all doctors. Now, all the drug names that can be easily confused are listed in our Manual.

In addition, the Committee emphasized the verification of ampules containing active drugs, especially dangerous drugs, at meetings of the department head.

I think that it is not possible to avoid mistakes such as mistaking a 1,000 mg ampule for a 100 mg ampule in a busy emergency department even though the volumes are obviously different.

I asked Astra Japan, a distributor of Xylocaine to make the difference in ampule volume more distinguishable both visually and impressibly. I even suggested that the 1,000 mg ampules could be triangular in shape. After around two months, I received a polite letter from the company saying that as they distributed medicines all over the world, they could not change their dosage forms for financial reasons. They said they would take my suggestion into consideration in future revisions. After all, they did nothing.

Further investigation revealed that many medicines are contained in ampules of the same shape. I hope that it would be possible to differentiate between these same-shaped ampules by making changes such as the addition of a few grooves as a minimum distinguishable mark.

The same thing can be said for oral medicines. For four years, I continually appealed to manufacturers regarding my concern that many oral medicines are similarly packaged. Packages or dosage forms should be designed

to be distinguished easily. For example, a red-based design for cardiovascular medicines, a yellow-based design for gastroenterological medicines, and a blue-based design for respiratory medicines. I believe that the pharmaceutical industry should seriously tackle this problem for the sake of risk management.

As the pharmaceutical industry is involved in commercial practices, it is the task of the Pharmaceutical and Medical Safety Bureau of the Ministry of Health and Welfare to supervise them.

Let me introduce another case of antibiotics overdosing.

A doctor ordered two types of antibiotics. The hospital has only two sizes of prescription forms with a similar basic format. The doctor ordered the administration of medicine A twice a day, and medicine B once a day on the same form. The time of administration was not set according to nurses' convenience. The incident happened in a ward where medicine A and B are reportedly often co-administered.

As the prescription form showed just '2' meaning 'twice a day' in the section for the administration time of medicine A, a nurse wrote in 2 a.m. and 2 p.m. The nurse was thinking of the same idea when she wrote the same thing for medicine B and started double the dose of medicine B. After about 2 days, she realized the mistake.

In response to this incident, the Committee established an integrated system for describing injections in the order form. Up to then, individual doctors had filled the form in at their own discretion. Subsequently, doctors were asked to fill in the form showing the actual administration time.

Doctors were asked to write the exact time of administration, or mornings and evenings for medicines for which the time is not designated and is at the discretion of the nurses. For medicines that should be administered once a day, they were asked to write the exact time, or mornings or evenings.

Establishment of a Risk Management System

Medical malpractice can be considered from the two perspectives, from that of a medical institution or an individual.

A medical institution should assign a general risk manager to establish a risk management system (Table 1). A president or vice-president should undertake the responsibility for this. Because hospital systems sometimes require modification for this purpose, an administrator should be responsible for implementation.

Next, department heads or head nurses should be made aware of their position as risk managers in the department or division.

I believe that the most appropriate method is the incident reporting system in order to gather internal information.

In addition, a committee for reviewing incident reports such as a risk management committee should be organized. The conclusion of such a committee based on incident reports can be of benefit to the whole hospital through a feedback system.

Furthermore, this committee can also function as a means of medical audit.

I call this the third eye. The possibility of a review of cases by 11 doctors from 11 departments encourages the medical staff to conduct medical practices with more care.

Additionally, medical records should be kept precisely based on the facts. Medical practices should also be standardized as much as possible. Clinical pathway has recently become more prevalent in Japanese hospitals. By reducing the potential for mistakes, standardization is very important in improving not only economic factors in health care, but also the quality of medical treatment.

The "Manual to Prevent Medical Accidents" mentioned before should be developed as a risk prediction system. Our manual provides the principles for the prevention of medical malpractice in a general statement. It includes the basic appropriate manners and behavior for a

Table 1 Risk Management by a Medical Institution

1) Appointment of a general risk manager
   Responsible administrator (President or vice-president)
2) Assignment of risk managers
   Department heads, head nurses, and division heads
3) Collection of information
   Incident reporting system
4) Medical Risk Management (MRM) Committee
   1) Reviewing incident reports:
      Medical technique, judgement, working conditions, human factors (background)
   2) Feedback of conclusions: information shared by the whole hospital
   3) Medical audit: Institutional monitoring
5) Correct recording based on facts
6) Standardization of medical treatment: utilization of clinical pathway
7) Establishment of a risk prediction system
   Development of a manual for the prevention of medical malpractice
   Principles for the prevention of medical malpractice:
      manner and behavior of doctors, patient-oriented thinking, importance of confirmation
8) Introduction of checking systems into the institutional systems
9) Education of doctors, nurses, and medical staff
   Fostering risk managers
   Guidance to incoming doctors
   Guidance for residents

doctor, patient-oriented thinking, importance of confirmation, a responsive attitude for listening to colleagues and medical co-workers, establishment of a relationship with mutual trust between the doctor and patient, and the means of obtaining informed consent.

It is also important to incorporate a checking system into the institutional system. Pharmacists and nurses contribute to this in the Musashino Red Cross Hospital.

Finally, education of the medical staff is extremely important. As almost 40 new doctors come into the hospital every year, special guidance for incoming doctors has been given twice a year as well as for residents. I make a speech using the Manual to Prevent Medical Accidents on these occasions.

It is quite difficult to foster risk managers. I am struggling to appropriately raise the awareness of managers in this regard.

Risk Management by Individuals

To establish risk management systems at the individual level (Table 2), QC (Quality Control) activity is one of the best methods of raising the awareness of medical professionals even though we failed to introduce it in the first two years.

It should be understood that incident reports are a basis for improvement of the institutional system, and that they are not to be used as a means of reprimand. We encourage medical professionals to write the reports honestly as writing these reports helps raise awareness.

The third revision of the "Manual to Prevent Medical Accidents" has recently been completed. The drafting by risk managers of preventive measures for listed accidents that are most likely to occur also helps raise awareness, and we do not aim at completion of a perfect manual. It will also be revised in a few years.

I repeatedly emphasize this, the basic attitude such as manner and behavior, patient-

Table 2 Risk Management by Individuals

1) To raise the awareness of medical professionals
   Raising the awareness through QC (Quality Control) activities and incident reports
   Listing accidents that are most likely to occur, and formulating preventive measures
   Development of a Manual to prevent medical accidents
2) Manner and behavior of the doctors and medical staff, patient-oriented thinking, importance of confirmation, humility, awareness
3) Communication (reduction of human error)
   Medical staff and patients
   Among medical professionals (between doctors and nurses, doctors and technicians, nurses and technicians): horizontal person to person relationships with mutual monitoring

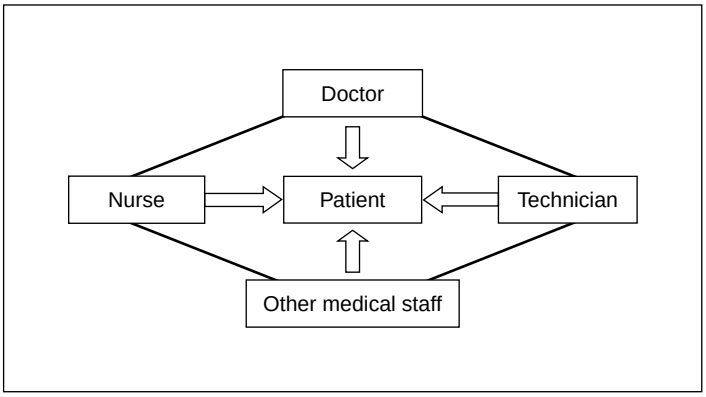

Fig. 1 Relationship with patients

oriented thinking, importance of confirmation, and a humble attitude on the part of medical professionals, is important.

Awareness, a factor that is emphasized in the field of aviation, is the basis for communication, leading to CRM (crew resource management). Every communication is indispensable; one between medical professionals and the patients, as well as among medical professionals, such as doctors and nurses, doctors and technicians, and nurses and technicians. All these communications should be on an equivalent level. In fact, however, there is always attempt to distinguish each rank vertically among medical staff.

This vertical relationship should be converted to a parallel or horizontal one (Fig. 1). Human errors resulting from unavoidable human factors, such as memory decline and misunderstandings, should not cause major accidents if the warnings from those around us are accepted.

I think that the relationship among medical professionals is extremely important.

Characteristics of Medical Disputes

There are some common characteristics in medical disputes. As a lawyer involved in medical disputes often said, while half of the medical disputes involve a financial settlement, the other half concern the personality of the doctor. Appeals are made just to punish the doctor. In fact, these kinds of cases seem to be increasing.

According to statistics in the United States,

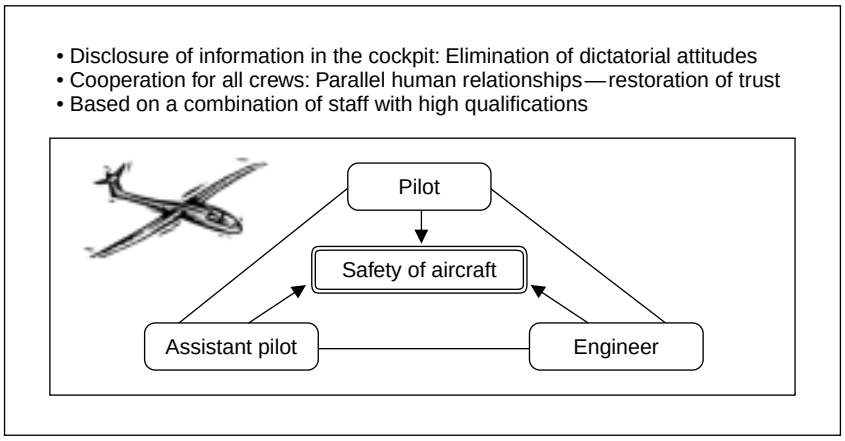

Fig. 2 CRM (Crew Resource Management)

70% of medical disputes arise even in the absence of errors on the part of the medical staff. They stem from a lack of communication between the medical professionals and the patients.

Although communication seems to be related to conversation, patients reportedly feel distrust based on expression of the face and eyes, as well as the behavior of medical professionals. An initial germ of distrust can grow gradually through consecutive medical treatment, finally leading to a medical dispute even in the absence of errors.

We cannot omit the factor of personal problems in cases of medical disputes. In fact, they are related to the quality, personality, and technical level of medical professionals.

Learning from the Risk Management System in the Field of Aviation[8–9)]

I will address some advantages of risk management technology in the field of aviation from which we can learn a lot. I have not yet implemented them, but I am planning to do so.

Risk management system in the field of aviation is called CRM (cockpit resource management). It is now called Crew Resource Management, which is a more comprehensive term (Fig. 2).

In a cockpit, there are three persons, a pilot, an assistant pilot and an engineer, and now there are two in almost all cases. CRM aims at utilizing every item of information and resources in a cockpit to the greatest extent possible. In the past, as pilots had absolute authority, no other crews were available to warn them and this often resulted in accidents.

In CRM, it is most important to develop a parallel relationship between crews in the cockpit in order to avoid human errors. The training system for this is called LOFT (Line Oriented Flight Training). In the simulator, three crews operate an aircraft in various settings from Tokyo to Osaka, for example. They review the recorded flight process, and find some means of improving the situation by themselves. I think that this can be introduced into the medical field.

The awareness that I mentioned before is on the basis of teamwork. It is important to consider other people's problems as your own, to pay continuous attention to the surroundings, and to exchange information. In addition, what is required of the pilot as the leader is clearly established. This can be applied to doctors.

A pilot should be a confident person capable of being responsible for his or her actions, a self-controlled person based on creative judgment, a person with a high learning capacity,

Table 3 Practical Approaches to Human Factors in ANA

7 points to prevent field errors
1. *Self-monitoring* with a humble attitude
2. *Team-monitoring* with sensitive attention to others
3. Raising *awareness* in unusual and high-risk conditions
4. Information sharing through *sufficient communication*
5. *Risk prediction* leading to safety
6. *No violation* of basic understandings
7. *Proposals for improving* oneself and others

and a person who can detect the problem and resolve it by himself or herself. This can also be applied to doctors.

In conclusion, a leader should be a self-controlled person. An organization consisting of people with self-control can flexibly response to various crises or pressures and overcome various obstacles. Therefore, the field of aviation reportedly emphasizes the fostering of self-controlled people.

In the medical field, the doctor is responsible for the cure, the nurse for care, and the technician provides skills to ensure the safety of patients. Other staff involved in the medical field, including clerks, all contribute to the treatment of patients.

Based on this concept, a parallel relationship to allow free mutual monitoring can be established by recognizing that all staff including doctors, nurses, technicians and others have their own roles to play. This mutual monitoring only is a matter of preventing normal human errors.

The techniques of the pilot are divided into flying skills and "airmanship". The term "airmanship" originated from noblésse oblíge, what is called aristocracy in the United Kingdom, meaning leadership based on quality, morality, responsibility and obligation. It is as highly desirable a quality as operating skills.

This can be applied to doctors. Doctors are required to have both medical expertise and medical skills, and "doctormanship," which is a humane quality and involves a sense of obligation and responsibility. This has not been emphasized in medical education in Japan.

7 Points to Prevent Errors

All Nippon Airways (ANA) distribute "7 points to prevent field errors" to employees, as a practical approach to dealing with human factors (Table 3). I take it up because it can be applied to the medical field.

1) Self-monitoring with a humble attitude, 2) team-monitoring with sensitive attention to others, 3) raising awareness in unusual and high-risk conditions, 4) information sharing though sufficient communication, 5) risk prediction leading to safety, 6) no violation of basic understandings, 7) proposals for improving oneself and others.

I believe that these can be combined into the concept of transparency in medicine. In other words, it concerns recording, accountability, patient-oriented medicine, and disclosure of information.

The hospital convenes a Medical Council consisted of the president, vice-president, head of the nursing department, corporate secretary, and chief manager of the general section to discuss corrective measures when a medical dis-

pute occurs. I serve as the general risk manager, supported by a Risk Management Committee consisting of 15 members including doctors, pharmacists, laboratory technicians, clerks and risk management nurses.

I have spoken about the control and prevention of medical malpractice based on experiences at the Musashino Red Cross Hospital. Thank you for listening.

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