

- adults. Washington, DC: American Psychological Association, 1986:213-217.
8. Niino N, Imaizumi T, Kawakami N. A Japanese translation of Geriatric Depression Scale. *Clin Gerontol* 1991; 10:85-87.
  9. Cwikel J, Ritchie K. Screening for depression among the elderly in Israel: an assessment of the Short Geriatric Depression Scale (S-GDS). *Isr J Med Sci* 1989; 25:131-137.
  10. Herrmann N, Mittmann N, Silver I, et al. A validation study of the geriatric depression scale short form. *Int J Geriatr Psychiatry* 1996; 11:457-460.
  11. Almeida OP, Almeida SA. Short versions of the geriatric depression scale: a study of their validity for the diagnosis of a major depressive episode according to ICD-10 and DSM-IV. *Int J Geriatr Psychiatry* 1999; 14:858-865.
  12. Schreiner AS, Morimoto T, Asano H. Depressive symptoms among poststroke patients in Japan: frequency distribution and factor structure of the GDS. *Int J Geriatr Psychiatry* 2001; 16:941-949.
  13. AGS Public Policy Committee. Comprehensive geriatric assessment. *J Am Geriatr Soc* 1989; 37:473-474.
  14. Health and Public Policy Committee, American College of Physicians. Comprehensive functional assessment for elderly patients. *Ann Intern Med* 1988; 109:70-72.
  15. Mahoney FI, Barthel DW. Functional evaluation: the Barthel Index. *Md State Med J* 1965; 14:61-65.
  16. Lawton MP, Moss M, Fulcomer M, et al. A research and service oriented multilevel assessment instrument. *J Gerontol* 1982; 37:91-99.
  17. Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975; 12:189-198.
  18. Schreiner AS, Hayakawa H, Morimoto T, et al. Screening for late life depression: cut-off scores for the Geriatric Depression Scale and the Cornell Scale for Depression in Dementia among Japanese subjects. *Int J Geriatr Psychiatry* 2003; 18:498-505.
  19. Ozawa T. Comprehensive geriatric assessment. *Jpn J Geriatr* 1996; 35:1-9.
  20. Muraoka Y, Oiji A, Ihara K. The physical and psychological and social background factor of elderly depression in the community. *Nippon Ronen Seishin Igakkai Zasshi* 1996; 7:397-407.
  21. Patrick L, Knoefel F, Gaskowski P, et al. Medical comorbidity and rehabilitation efficiency in geriatric inpatients. *J Am Geriatr Soc* 2001; 49:1471-1477.
  22. Kotila M, Numminen H, Waltimo O, et al. Depression after stroke: results of the FINNSTROKE Study. *Stroke* 1998; 29:368-372.
  23. Carson AJ, MacHale S, Allen K, et al. Depression after stroke and lesion location: a systematic review. *Lancet* 2000; 8:122-126.
  24. Aneshensel CS, Frerichs RR, Huba GJ. Depression and physical illness: a multiwave, nonrecursive causal model. *J Health Soc Behav* 1984; 5:350-371.
  25. Berkman LF, Berkman CS, Kasl S, et al. Depressive symptoms in relation to physical health and functioning in the elderly. *Am J Epidemiol* 1986; 124:372-388.
  26. Wells KB, Stewart A, Hays RD, et al. The functioning and well-being of depressed patients. Results from the Medical Outcomes Study. *JAMA* 1989; 262(7): 914-919.
  27. Ormel J, Rijdsdijk FV, Sullivan M, et al. Temporal and reciprocal relationship between IADL/ADL disability and depressive symptoms in late life. *J Gerontol B Psychol Sci Soc Sci* 2002; 57:338-347.
  28. Katz IR. Diagnosis and treatment of depression in patients with Alzheimer's disease and other dementias. *J Clin Psychiatry* 1998; 59(Suppl 9):38-44.
  29. Fischer P, Simanyi M, Danielczyk W. Depression in dementia of the Alzheimer type and in multi-infarct dementia. *Am J Psychiatry* 1990; 47:1484-1487.
  30. Rovner BW, Broadhead J, Spencer M, et al. Depression and Alzheimer's disease. *Am J Psychiatry* 1989; 146:350-353.
  31. Liu CY, Wang SJ, Teng EL, et al. Depressive disorders among older residents in a Chinese rural community. *Psychol Med* 1997; 27:943-949.
  32. No authors listed. Grief versus depression in elderly patients. *JAMA* 1979; 241:1558.
  33. Phifer JF, Murrell SA. Etiologic factors in the onset of depressive symptoms in older adults. *J Abnorm Psychol* 1986; 95: 282-291.
  34. Stuck AE, Siu AL, Wieland GD, et al. Comprehensive geriatric assessment: a meta-analysis of controlled trials. *Lancet* 1993; 23:1032-1036.

ORIGINAL ARTICLE

# Long-term prognosis and satisfaction after percutaneous endoscopic gastrostomy in a general hospital\*

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**Background:** Percutaneous endoscopic gastrostomy (PEG) has been widely acknowledged as a safer method for enteral feeding; however, its long-term impact on prognosis and quality of life in elderly patients is not sufficiently understood. There are issues still to be studied regarding the indications for PEG, due to the lack of convincing evidence that it reduces expected complications such as aspiration pneumonia or for improving the prognosis of patients with severe dementia.

**Method:** In this study we investigated the survival rate after PEG and the families' satisfaction in 78 inpatients who underwent PEG. We conducted the investigation by sending questionnaires to the families.

**Results:** The results for the 69 cases (88%) in which the patient recovered showed that the 1-year survival rate was 64.0%, and the 2-year survival rate was 55.5%. Fifty-three per cent of patients' families indicated overall satisfaction regarding of PEG.

**Conclusions:** The survival rates were relatively higher than those from previously reported studies. This may be attributed to variations in patients' clinical, socio-economic, or cultural backgrounds in therapeutic interventions. We recognized the importance of clarifying factors that would affect the living and functional prognosis and quality of life in elderly patients who underwent PEG. The indications for PEG are based on a comprehensive assessment of the relevant factors in individual cases, and by taking patients' and families' wishes into consideration.

**Keywords:** gastrostomy, personal satisfaction, survival rate.

## Introduction

Recently, as the technique of enteral nutrition has developed, it has helped patients with dysphagia caused by stroke, neurological degenerative disorders etc., to sur-

vive longer. Percutaneous endoscopic gastrostomy (PEG) is a widely-used method for introducing a gastrostomy tube to enable enteral feeding in patients who are unable to eat. Since it was first described by Gauderer *et al.* in 1980,<sup>1</sup> PEG has spread widely and rapidly, including in Japan. The operation is comparatively safe and once successfully performed, nutrition can be administered in a reliable way. Although many reports regarding the utility of PEG have been published, some studies have indicated that PEG did not reduce the risk of aspiration pneumonia and did not improve the life expectancy of patients with high cognitive disorders. Because PEG is an invasive therapy, physicians should consider the risks and benefits of the operation carefully

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and should confer with the patient and the patient's family, giving them adequate information before obtaining their agreement to the operation.

Although the short-term benefits have been well documented, the long-term survival rate is still unclear. In the present study we investigated the long-term survival rate and the families' satisfaction after PEG retrospectively in a general hospital.

## Materials and methods

The data were collected in Anjo-Kosei Hospital, which is a key general hospital in the west Mikawa area. The hospital has 680 beds, and is mainly used for the treatment of acute diseases. We collected data retrospectively from patients who underwent PEG from February 1998 to August 2000. The questionnaire was sent to patients or their families in February 2001. The shortest period of follow-up for the dead cases and survivors, were 4 days and 157 days respectively. The longest period of follow-up was 1078 days among survivors. The questionnaire consisted of five questions: (i) Is the patient alive or dead? (ii) (If the patient is already dead) When did the patient die? (iii) Was the patient admitted to the hospital because of pneumonia after PEG? (iv) Are family satisfied with PEG placement? (v) Who is the main caregiver?

In all cases, PEG ( $n = 78$ ) was performed on patients who were unable to eat due to dysphagia or highly cognitive impairment. In every patient, PEG was inserted by a pull-through method, using the BARD Fastrack PEG kit (Medicone Inc., Osaka). A complete esophagogastroduodenoscopy was performed with PEG in each patient. The point at which to perform gastrostomy was chosen by finger-pushing and transillumination of the abdominal wall, and confirmed by X-ray.

Statistical analysis was performed by using Statview (SAS Inc., Cary, NC). The non-parametric data were analyzed by the Mann-Whitney test for more than two groups, and by Fisher's exact test between two groups. Survival rates were analyzed by Kaplan-Meier's survival curve, and differences between the groups in survival curves were assessed with the log-rank test.

## Results

We received 69 replies out of 78 questionnaires (88%). All of the 69 answered the question as to whether the patient was alive or dead, with 40 patients still alive and 29 patients dead. We learned from their charts that three of the nine patients who did not reply were alive and five were dead, but one had no follow up information whatever. The mean age of the patients when PEGs were performed was  $75.7 \pm 14.1$  (mean  $\pm$  SD) years.

In the present study, the most common disease leading to the performance of PEG was cerebrovascular dis-

ease. Fifty-one of 69 patients (65%) had suffered from this disease. As for the rest, there were 11 patients (14%) with neurodegenerative disorders (two with Parkinson's disease, two with amyotrophic lateral sclerosis, two with senile dementia of the Alzheimer's type, one each with olivopontocerebellar atrophy/Creutzfeldt-Jakob disease/Pick's disease/adrenoleukodystrophy, six patients (8%) with hypoxemia due to cardiac arrest or complications from heart surgery, three patients (4%) with brain tumors, two patients with (2%) malignancy, two patients (2%) with pneumonia, and three (4%) suffering from other diseases (polymyositis/dermatomyositis, renal failure, Down's disease). In two cases, the patient suffered from peritonitis during the perioperative period, but in both cases the peritonitis subsided soon after the tube was withdrawn. One of these two became able to ingest food orally, while the other's nasogastric tube is still in place. Both were alive at the time of the investigation. No deaths were attributable to the PEG procedure. Three of the 78 patients died in the first 14 days.

## Prognosis

The rate of survival, according to the questionnaire, was 91.3% after 30 days, 64.0% at 1 year, and 55.5% at 2 years. Figure 1 shows Kaplan-Meier's survival curve after PEG. There were no significant differences in survival rates between genders ( $P = 0.764$ ), diseases; stroke versus non-stroke ( $P = 0.604$ ), or the presence of pneumonia ( $P = 0.430$ ).

We received 62 answers regarding hospitalization due to pneumonia after PEG, and among these, 17 patients (27%) had been admitted.

## Satisfaction

We received 64 answers regarding the families' satisfaction after PEG. Of these 34 families (53%) answered 'yes', six families (9%) answered 'no', and 24 families (38%) answered 'cannot say yes or no.' There were no

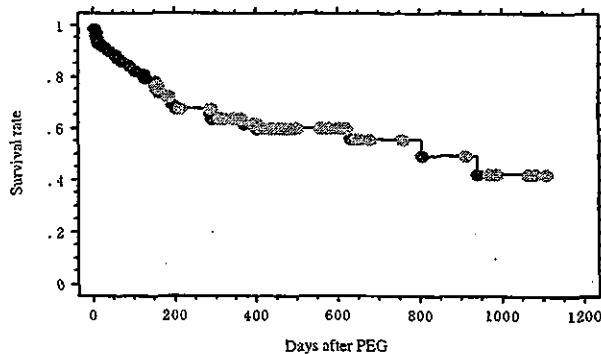


Figure 1 Kaplan-Meier's survival curve after percutaneous endoscopic gastrostomy (PEG). (●, censored (dead) cases ○, uncensored (alive) cases.)

Table 1 Summary of the literature about survival rates after percutaneous endoscopic gastrostomy (PEG)

Author	Year	Nationality	n	Age (mean $\pm$ SD)	Prior diagnoses	Treatment	1-Year survival rate (%)	2-Year survival rate (%)
Ciocon <i>et al.</i> <sup>3</sup>	1988	USA	70	82.0	Refusal to swallow 50%, dysphagia 47%, esophageal obstruction 3%	Nasogastric tubes, Gastrostomy	60 (11 month)	NA
Taylor <i>et al.</i> <sup>4</sup>	1992	USA	97	76.5 (median)	stroke 48%, other neurological disease 25%	PEG	35 (1.5 yr)	NA
Chowdhury <i>et al.</i> <sup>5</sup>	1996	Australia	50	Male 50, Female 61 (median)	Neurological disease 52%	PEG	38	NA
Rabeneck <i>et al.</i> <sup>6</sup>	1996	USA	7 369	68.1	Stroke 19%, other neurological disease 29%	PEG	41	29
Howard <i>et al.</i> <sup>7</sup>	1997	USA	786	79.1 $\pm$ 7.6	Not described	Home enteral nutrition	45	NA
Loser <i>et al.</i> <sup>8</sup>	1998	Germany	210	61.3 $\pm$ 15.3	Neurological diseases 47%, ear-nose-throat disease 29%	PEG	34	NA
Grant <i>et al.</i> <sup>9</sup>	1998	USA	81 105	65-74 (25%), 75-84 (41%), 85 (33%)	Stroke 18%, neoplasms 9%, fluid and electrolyte disorders 9%	Gastrostomy	37	NA
James <i>et al.</i> <sup>10</sup>	1998	UK	126	80 (median)	Stroke	PEG	47	NA
Fisman <i>et al.</i> <sup>11</sup>	1999	USA	175	65-74 (64%), 75-84 (18%), 85 (18%)	Stroke 36%, neoplasms 31%, pneumonia 23%	PEG	39	NA
Callahan <i>et al.</i> <sup>12</sup>	2000	USA	150	78.9 $\pm$ 8.1	Stroke 41%, other neurological disease 25%, neoplasms 13%	PEG	50	NA
Verhoef <i>et al.</i> <sup>13</sup>	2001	Canada	112	66.0 $\pm$ 17.9	Head injury or stroke 62%, neoplasms 17%	PEG	61	NA

significant differences in the families' satisfaction among the groups according to patients' age ( $P = 0.690$ ), gender ( $P = 0.329$ ), the occurrence of pneumonia ( $P = 0.268$ ) or the patients' life or death at the time of the research ( $P = 0.060$ ).

## Discussion

Recently PEG has become more popular for patients with dysphagia. PEG is effective for preventing patients with severe dysphagia from starving; however, it is possible that some patients undergo the operation against their desire not to prolong their lives, which causes controversy over the indication of PEG.

Finucane *et al.* meta-analyzed the prognosis of patients with severe dementia after PEG, from reports completed before March 1999.<sup>2</sup> They insisted on physicians' modesty in performing PEG, as their analysis could not show a reduction in the occurrence of pneumonia or the prolongation of life after PEG. However, this study was no more than an outline, as their analysis did not consider the reasons for dementia, the degree of medication, the type of hospital or other details.

Table 1 shows the results of some leading reports showing more than a 1-year prognosis.<sup>3-13</sup> These showed that 1-year survival rates after PEG were 34-67%. A few reports of this kind can be found in Japan. Ishimura *et al.* analyzed the data from 87 of 95 patients who underwent PEG between 1993 and 1998 in a general hospital, and they reported that the 1-year survival rate was 38.2%, and the 2-year survival rate was 22.2%.<sup>14</sup> We sent a questionnaire to the families of patients who had undergone PEG, and we received a high response rate of 88%. Even though the subjects of the present study were old, the mean age was 75.7 years, the 1-year and 2-year survival rates were 64.0% and 55.5%, respectively, which are higher than those found in previous studies. This finding is likely related to the development of the operation technique or the kind of medicine used.

Norberg *et al.* compared the thoughts of nurses on enteral nutrition for people with severe dementia in the United States, Australia, Canada, China, Finland, Israel and Sweden.<sup>15</sup> There were a few cultural differences in the results, as most of the nurses except those from China deemed autonomy the most important factor. Though it is unclear how the kind of medical practice may differ among these countries and Japan, it is possible that such a difference might affect the indication of PEG or the prognosis after PEG.

Additionally, we investigated the families' satisfaction after PEG. Families were asked the question 'Are you satisfied that your family underwent PEG?' and over half of the families answered 'Yes'. But among the responses there were some additional negative remarks, such as, 'it was inevitable because the patient could not

eat.' Because some families visited Anjo-Kosei Hospital in order to take treatments for themselves, we have to interpret the results carefully. In particular, it is difficult to determine the feelings of the patients after PEG because most of them are not able to communicate due to the disease. In 1996, Matsushita *et al.* asked outpatients whether they would be willing to take enteral nutrition in the case that they should become unable to eat or communicate due to severe disease.<sup>16</sup> They reported that only 8.7% of the outpatients showed that they were willing to take enteral nutrition in such a state. Although it is not clear how many patients take enteral nutrition against their will, it is possibly not a small number. The dissociation between the rate of patients taking enteral nutrition and their willingness to accept it might be due to clinical and ethical problems or to a lack of knowledge about enteral nutrition among the patients, but there are many clinical and ethical points to be clarified, such as the effect of enteral nutrition on patients' quality of life. Just as Kanie *et al.* investigated and were able to report an improvement of the quality of life of patients after PEG,<sup>17</sup> we should make more of an effort to clarify the effects on patients of enteral nutrition, including PEG, with a view to determining not only their prognosis of life expectancy but also their functional prognosis and their quality of life.

In conclusion, we investigated the survival rates of patients after PEG and their families' satisfaction. The 1-year and 2-year survival rates were relatively higher than those from previous studies, being 64.0% and 55.5%, respectively. Fifty-three percent of the patients' families showed overall satisfaction regarding the taking of PEG. The higher survival rates observed in this study may be attributed to variations in patients' clinical, socio-economic or cultural backgrounds in therapeutic interventions. We recognize the importance of clarifying factors that would affect the living and functional prognoses and quality of life of elderly patients who have undergone PEG. The indication for PEG can be made based on a comprehensive assessment of the relevant factors in individual cases, and by taking the patient's and the patient's family's wishes into consideration.

## References

- 1 Gauderer MW, Ponsky JL, Izant RJ Jr. Gastrostomy without laparotomy: a percutaneous endoscopic technique. *J Pediatr Surg* 1980; 15: 872-875.
- 2 Finucane TE, Christmas C, Travis K. Tube feeding in patients with advanced dementia: a review of the evidence. *JAMA* 1999; 282: 1365-1370.
- 3 Ciocon JO, Silverstone FA, Graver LM, Foley CJ. Tube feedings in elderly patients. Indications, benefits, and complications. *Arch Intern Med* 1988; 148: 429-433.
- 4 Taylor CA, Larson DE, Ballard DJ *et al.* Predictors of outcome after percutaneous endoscopic gastrostomy: a community-based study. *Mayo Clin Proc* 1992; 67: 1042-1049.

### Long-term prognosis after PEG in a general hospital

- 5 Chowdhury MA, Batey R. Complications and outcome of percutaneous endoscopic gastrostomy in different patient groups. *J Gastroenterol Hepatol* 1996; **11**: 835-839.
- 6 Rabeneck L, Wray NP, Petersen NJ. Long-term outcomes of patients receiving percutaneous endoscopic gastrostomy tubes. *J General Intern Med* 1996; **11**: 287-293.
- 7 Howard L, Malone M. Clinical outcome of geriatric patients in the United States receiving home parenteral and enteral nutrition. *Am J Clin Nutr* 1997; **66**: 1364-1370.
- 8 Loser C, Wolters S, Folsch UR. Enteral long-term nutrition via percutaneous endoscopic gastrostomy (PEG) in 210 patients: a four-year prospective study. *Dig Dis Sci* 1998; **43**: 2549-2557.
- 9 Grant MD, Rudberg MA, Brody JA. Gastrostomy placement and mortality among hospitalized Medicare beneficiaries. *JAMA* 1998; **279**: 1973-1976.
- 10 James A, Kapur K, Hawthorne AB. Long-term outcome of percutaneous endoscopic gastrostomy feeding in patients with dysphagic stroke. *Age Ageing* 1998; **27**: 671-676.
- 11 Fisman DN, Levy AR, Gifford DR, Tamblyn R. Survival after percutaneous endoscopic gastrostomy among older residents of Quebec. *J Am Geriatr Soc* 1999; **47**: 349-353.
- 12 Callahan CM, Haag KM, Weinberger M *et al*. Outcomes of percutaneous endoscopic gastrostomy among older adults in a community setting. *J Am Geriatr Soc* 2000; **48**: 1048-1054.
- 13 Verhoef MJ, Van Rosendaal GM. Patient outcomes related to percutaneous endoscopic gastrostomy placement. *J Clin Gastroenterol* 2001; **32**: 49-53.
- 14 Ishimura N, Hashimoto T, Wada T *et al*. [A clinical study of 95 percutaneous endoscopic gastrostomy cases.] *Koritsu Unnan Sogobyojin Igakuzasshi* 2000; **8**: 1-6. (In Japanese.)
- 15 Norberg A, Hirschfeld M, Davidson B, Davis A, Lauri S, Lin JY. Ethical reasoning concerning the feeding of severely demented patients: an international perspective. *Nurs Ethics* 1994; **1**: 3-13.
- 16 Matsushita S, Inamatsu T, Hashimoto H *et al*. [Elderly outpatients' attitudes toward care in terminal stage disease.] *Nippon Ronen Igakkai Zasshi* 1999; **36**: 45-51. (In Japanese.)
- 17 Kanie J, Kono K, Yamamoto T *et al*. [Usefulness and problems of percutaneous endoscopic gastrostomy in a geriatric hospital.] *Nippon Ronen Igakkai Zasshi* 1998; **35**: 543-547. (In Japanese.)

## Effects of home massage rehabilitation therapy for the bed-ridden elderly: a pilot trial with a three-month follow-up

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**Objectives:** To assess the effects of home massage rehabilitation therapy on the bed-ridden elderly.

**Design:** Alternately allocated trial.

**Setting:** Subjects' homes, three home nursing stations, 13 visit care stations and one day service centre in Aichi prefecture, Japan.

**Subjects:** Bed-ridden patients who were 65 years and above, no dementia, stable general condition, and no rehabilitation therapy.

**Intervention:** Thirty-minute sessions of home massage rehabilitation therapy by a massage practitioner 2 or 3 days a week for three consecutive months or usual care.

**Main measurements:** Barthel Index (BI), Subjective Satisfaction and Refreshment Scale, Apathy Scale and Self-rating Depression Score.

**Results:** Fifty-three subjects were recruited, 26 in the home massage rehabilitation group (HMG) and 27 in the routine care group without massage (RCG). The protocol was completed for 40 subjects, 22 in the HMG and 18 in the RCG. There were no significant differences between the baseline characteristics of both groups; age, presence of spouse living together, diseases associated with disabilities and use of day care rehabilitation ( $p = 0.76, 0.36, 0.94$  and  $0.71$ , respectively). The total BI score of the HMG ( $15.27 \pm 4.51$ ) at baseline was nonsignificantly lower ( $p = 0.03$ ) than those of the RCG ( $11.44 \pm 5.90$ ). Subjective satisfaction and refreshment scale, Apathy Scale and Self-rating Depression Score of both groups at baseline were matched ( $p = 0.12, 0.32$  and  $0.89$ , respectively). There were no statistical differences between the intergroup changes over time in BI, Subjective Satisfaction and Refreshment Scale, Apathy Scale and Self-rating Depression Score ( $p = 0.35, 0.08, 0.70$  and  $0.55$ , respectively).

**Conclusion:** Home massage rehabilitation therapy did not show a positive effect on the bed-ridden elderly mentally and physically. We would require large-size trials to determine whether it is effective.

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## Introduction

A byproduct of the ageing of the population has been a rise in bed-ridden patients who remain at home.<sup>1,2</sup> However, it is currently difficult to adequately meet the demand for home rehabilitation services for the bed-ridden elderly staying at home due to a shortage of physical therapists and occupational therapists.<sup>1,3-6</sup> Home massage rehabilitation therapy by trained professionals is available to the bed-ridden elderly as an alternative home rehabilitation service in Japan.

Massage has been used since ancient times both in the East and the West.<sup>7,8</sup> Recently, the demand for massage therapy as a useful adjunct to medical treatment has been on the rise in the US.<sup>9-12</sup>

There is now a need for 'evidence-based alternative medicine' in addition to evidence-based medicine.<sup>7,10,13,14</sup> Various countries, including the US, have encouraged research into the effects of alternative medicine.<sup>11,13,15</sup> We believe it is important to perform further studies for a more reliable evaluation of the effect of alternative medicine in Japan. A number of papers have highlighted the positive effects of massage treatments.<sup>7,16-21</sup>

However, to our knowledge, no study has reported on the effect of home massage rehabilitation therapy on the bed-ridden elderly. We therefore conducted a pilot study to evaluate the effect of home massage rehabilitation therapy on the following: activity of daily living (ADL), quality of life (QOL), apathetic mood and depressive mood of the bed-ridden elderly in communities.

## Methods

### Patient selection

Study participants were recruited for a period of nine months, from June 2002 to February 2003 from groups of users of home nursing stations, visit care stations and a day service centre in Aichi prefecture, Japan. We contacted service stations closest to our university and explained the study procedure to the director, chief administrator or head nurse. Staffs with one or more licences of nurse, physical therapist, occupational therapist or care manager were in charge of recruitment. The inclusion criteria were as follows: 65 years and above, cognitive impairment not likely to interfere

with adherence to the study, bed-ridden condition rank B or C; stable general condition and no rehabilitation therapy within three months of enrolment, and permission of the physician in charge. All eligible participants were required to agree to the study and sign informed consent forms.

The Japanese public nursing care system recently established the licence of care manager, whose primary responsibility is to oversee the co-ordination of care services for elderly people.

In Japan, the term 'bed-ridden' does not equate to being restricted to bed. Japan's Ministry of Welfare identifies four ranks of ADL of disabled elderly ranks B and C are defined as 'bed-ridden' condition in the criteria:

- Rank J = independent in ADL:  
Despite certain limitations, person is mostly independent in daily life and goes out on his/her own.
  - 1) Goes out using any means of public transportation.
  - 2) Goes out around the neighbourhood.
- Rank A = house-bound:  
In general, person can manage indoors independently, but requires some kind of care when going out.
  - 1) Goes out with assistance, and spends most of the day out of bed.
  - 2) Seldom goes out, and spends the day in and out of bed.
- Rank B = chair-bound:  
Requires some care indoors and spends most of the day in bed, but can maintain a seating position.
  - 1) Transfers to a wheelchair on his/her own and goes out of bed for meals and excretion.
  - 2) Requires assistance in transferring to a wheelchair.
- Rank C = bed-bound:  
Spends the whole day in bed, and requires assistance with excretion, eating meals and changing clothes.
  - 1) Turns over in bed on his/her own.
  - 2) Does not turn over in bed on his/her own.



### Allocation

We alternatively allocated the participants to either a home massage rehabilitation group (HMG) or a routine care group (RCG) in order of enrolment. Participants were enrolled in their order of appearance on a list of eligible applicants provided by each station. We commissioned each station to send us the list when participants' recruitment completed.

### Massage intervention

The HMG received 30-min sessions of home massage rehabilitation 2 or 3 days a week for 12 consecutive weeks. A local massage practitioner was assigned to each patient. Massage practitioners were selected by the professional Association of Licensed Massagers of Aichi prefecture. As a safety measure, the participants were given the option to stop receiving home massage rehabilitation therapy whenever they wished. Both HMG and RCG were also allowed to receive home rehabilitation and/or day care for the duration of the study.

The intervention of home massage rehabilitation consisted of medical massage and kinesitherapy as follows:

#### *Medical massage*

Medical massage included two kinds of massage: therapeutic massage and nursing massage.<sup>8</sup> Both consisted predominantly of rub and finger-pressure techniques.

- *Therapeutic massage* aims at the direct treatment of illnesses in internal medicine, orthopedics, neurology and other fields.
- *Nursing massage* aims at the indirect treatment of illnesses. It prevents or improves the patient's weakness or fatigue.

#### *Kinesitherapy*

- Sitting balanced exercise
- Sitting up exercise
- Standing up exercise
- Gait exercise
- Range of motion (ROM) exercise.

### Baseline and follow-up assessment

Assessments were performed at baseline and at three months. All participants were assessed by

qualified assessors having one or more licences of nurse, physical therapist, occupational therapist or care manager using the Barthel Index (BI),<sup>22</sup> Subjective Satisfaction and Refreshment Scale,<sup>23</sup> Apathy Scale<sup>3,24</sup> and Self-rating Depression Scale (SDS).<sup>25</sup> The Subjective Satisfaction and Refreshment Scale was assessed on a 4-item scale (3 = strongly, 2 = moderately, 1 = slightly, 0 = not at all) based on answers to the following question: 'To what extent do you feel satisfied and refreshed in daily life?' As for the apathy scale, we used the shortened edition of the apathy scale translated by Kobayashi. The scale consisted of 14 heads, and points were allotted to each question from 0 to 3. Higher scores reflect apathetic mood in this scale. The SDS was used to assess depressive mood.

The assessors were not blinded. They probably found out who was given intervention because they were staff from the participating stations usually providing home care for each participant.

### Statistical analysis

We analysed the significance of intergroup outcome differences at baseline. Proportions were compared by the  $\chi^2$  test. Continuous data was compared using the Mann-Whitney test. We also analysed the significance of the differences between intergroup changes over time by analysis of variance (ANOVA) with repeated measures. *p*-values < 0.01 were considered significant. Statistical analyses were performed with the Statview J-5.0.

## Results

### Profile of trial

We approached about 100 stations on participants' recruitment. Seventeen stations co-operated in the study. A total of 53 users were recruited for the trial, 26 in the HMG and 27 in the RCG. The subjects belonged to three home nursing stations, 13 visit care stations, and one day service centre in Aichi prefecture. At three months, the protocol was completed for 40 subjects, 22 in the HMG and 18 in the RCG. Four subjects were hospitalized, none in the HMG and four in the RCG. Nine subjects were lost to follow-up for personal or unknown reasons, four in the HMG and five in the RCG (Figure 1).

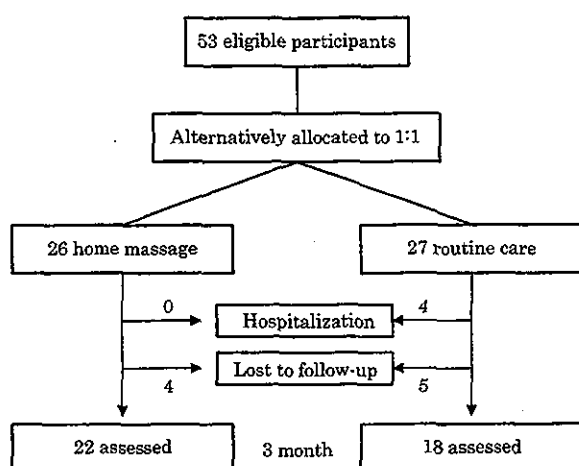


Figure 1 Flow diagram for the trial.

### Baseline characteristics

The baseline characteristics of the HMG and the RCG subjects followed up three months after enrolment are summarized in Table 1. The baseline characteristics of the subjects in the HMG and the RCG were matched for age, presence of spouse living together, diseases associated with disabilities and use of day care rehabilitation ( $p = 0.76$ ,  $0.36$ ,  $0.94$  and  $0.71$ , respectively). A stroke was the most frequent cause of disability in both groups ( $n = 12$  and  $12$ , respectively). The HMG ( $n = 14$ ) had a greater number of females than the RCG ( $n = 6$ ) ( $p = 0.06$ ).

### Main outcome measures

Table 2 shows main outcome measurements of subjects at baseline. The total BI score of the HMG ( $15.27 \pm 4.51$ ) at baseline was nonsignificantly lower than that of the RCG ( $11.44 \pm 6.0$ ) ( $p = 0.03$ ). In the Subjective Satisfaction and Refreshment Scale there was no significant difference between the baseline scores of the two groups ( $0.90 \pm 0.85$  and  $1.35 \pm 0.75$ , respectively). In the Apathy Scale there was no significant difference between the baseline scores of the two groups (18 and 23, respectively). In the SDS, there was no significant difference between the baseline scores of the two groups (45 and 46.5, respectively).

Table 3 shows main outcome measurements of subjects at three months. In BI there were no significant differences between the intergroup changes over time in the total ( $p = 0.35$ ) and each of 10 categories. In the Subjective Satisfaction and Refreshment Scale, Apathy Scale and SDS there were no differences between the intergroup changes over time between the two groups ( $p = 0.08$ ,  $0.70$  and  $0.55$ , respectively).

### Discussion

#### Outline and weaknesses of study

This study examined the effect of massage therapy, a traditional oriental medicine treatment, on at-home elderly in Japan. Despite extensive recruitment which lasted about nine months, the

Table 1 Baseline characteristics of subjects

Variable	HMG ( $n = 22$ )	RCG ( $n = 18$ )	$p$ -value
Age (mean $\pm$ SD) years	80.09 $\pm$ 8.09	79.67 $\pm$ 8.46	0.76
Female	14	6	0.06
Living with spouse	13	8	0.36
Family member (mean $\pm$ SD)	1.8	2.4	0.12
Going to day care	5	5	0.71
Cause of independence in ADL			0.94
Stroke	12	12	
Circulatory illness	2	2	
Respiratory illness	1	1	
Orthopaedic illness	6	3	
Rheumatism	1	1	

HMG, home massage rehabilitation group; RCG, routine care group.

Proportions were compared by the  $\chi^2$  test. Continuous data were compared using the Mann-Whitney test.

*Home massage rehabilitation for the bed-ridden elderly* 5**Table 2** Outcome measurements of subjects at baseline

Variable	HMG (n = 22)	RCG (n = 18)	p-value
BI (mean $\pm$ SD) (95% CI)			
Total (0–20)	15.27 $\pm$ 4.51 (13.27–17.27)	11.44 $\pm$ 5.90 (8.51–14.38)	0.03
Feeding (0–2)	1.77 $\pm$ 0.53 (1.54–2.01)	1.56 $\pm$ 0.71 (1.21–1.91)	0.40
Bathing (0–1)	0.46 $\pm$ 0.51 (0.23–0.68)	0.22 $\pm$ 0.43 (0.01–0.43)	0.21
Grooming (0–1)	0.73 $\pm$ 0.46 (0.53–0.93)	0.61 $\pm$ 0.50 (0.36–0.86)	0.53
Dressing (0–2)	1.50 $\pm$ 0.67 (1.20–1.80)	0.94 $\pm$ 0.73 (0.58–1.31)	0.03
Bowel (0–2)	1.64 $\pm$ 0.58 (1.38–1.89)	1.50 $\pm$ 0.86 (1.07–1.93)	0.92
Bladder (0–2)	1.41 $\pm$ 0.67 (1.11–1.70)	1.44 $\pm$ 0.78 (1.05–1.83)	0.73
Toilet use (0–2)	1.64 $\pm$ 0.58 (1.38–1.89)	1.06 $\pm$ 0.73 (0.69–1.42)	0.02
Transfers (0–3)	2.55 $\pm$ 0.67 (2.25–2.84)	2.00 $\pm$ 0.97 (1.52–2.48)	0.09
Mobility (0–3)	2.50 $\pm$ 0.80 (2.14–2.86)	1.50 $\pm$ 1.25 (0.88–2.12)	0.01
Stairs (0–2)	1.09 $\pm$ 0.68 (0.79–1.39)	0.72 $\pm$ 0.75 (0.35–1.10)	0.14
Subjective Satisfaction Scale (mean $\pm$ SD) (95% CI)	0.90 $\pm$ 0.85 (0.50–1.30)	1.35 $\pm$ 0.70 (0.99–1.71)	0.12
Apathy Scale (median) (95% CI)	18 (16–25)	23 (18–28.5)	0.32
SDS (median) (95% CI)	45 (42.5–49.5)	46.5 (38.5–50)	0.89

HMG, home massage rehabilitation group; RCG, routine care group.

There were no significant intergroup outcome differences at baseline (the Mann–Whitney test). *p*-values < 0.01 were considered significant.

sample size of the study was small for the following reasons: many users were already receiving home rehabilitation in the stations/centre, many users had dementia, and many users were reluctant to change to alternative allocation. The blindness was

limited because the station staff necessarily knew which group the participants were assigned to. We enlisted each station to perform the evaluation because of a shortage of staff and the large quantity of settings. This may have biased asses-

**Table 3** Outcome measurements of subjects at three months

Variable	HMG (n = 22)	RCG (n = 18)	p vs. baseline
BI (mean $\pm$ SD) (95% CI)			
Total (0–20)	15.05 $\pm$ 4.87 (13.25–18.02)	10.89 $\pm$ 6.29 (7.76–14.01)	0.35
Feeding (0–2)	1.64 $\pm$ 0.58 (1.38–1.89)	1.44 $\pm$ 0.71 (1.09–1.79)	0.37
Bathing (0–1)	0.50 $\pm$ 0.51 (0.27–0.73)	0.17 $\pm$ 0.38 (0.01–0.43)	0.33
Grooming (0–1)	0.82 $\pm$ 0.50 (0.60–1.04)	0.61 $\pm$ 0.50 (0.36–0.86)	0.53
Dressing (0–2)	1.50 $\pm$ 0.80 (1.14–1.86)	0.89 $\pm$ 0.76 (0.51–1.27)	0.90
Bowel (0–2)	1.59 $\pm$ 0.67 (1.30–1.89)	1.28 $\pm$ 0.83 (0.87–1.69)	0.85
Bladder (0–2)	1.41 $\pm$ 0.73 (1.08–1.73)	1.22 $\pm$ 0.88 (0.79–1.66)	0.63
Toilet use (0–2)	1.73 $\pm$ 0.63 (1.45–2.01)	1.17 $\pm$ 0.79 (0.78–1.56)	0.94
Transfers (0–3)	2.59 $\pm$ 0.67 (2.30–2.89)	1.94 $\pm$ 0.87 (1.51–2.38)	0.75
Mobility (0–3)	2.36 $\pm$ 0.90 (1.96–2.76)	1.39 $\pm$ 1.15 (0.82–1.96)	0.27
Stairs (0–2)	1.32 $\pm$ 0.72 (1.00–1.64)	0.78 $\pm$ 0.73 (0.41–1.14)	0.42
Subjective Satisfaction Scale (mean $\pm$ SD) (95% CI)	1.00 $\pm$ 0.80 (0.63–1.37)	1.00 $\pm$ 0.61 (0.69–1.31)	0.08
Apathy Scale (median) (95% CI)	23 (18.5–27.5)	25.5 (20.5–31)	0.70
SDS (median) (95% CI)	49 (45.5–51)	49.5 (41.5–55.5)	0.55

HMG, home massage rehabilitation group; RCG, routine care group; CI, confidence interval.

In all variables, there were no significant differences between intergroup changes over time by analysis of variance (ANOVA) with repeated measures. *p*-values < 0.01 were considered significant.

sors' evaluation and limited the validity of the results. Bed-ridden people in our inclusive criteria are more prone to dementia.<sup>26</sup> This may explain the presence of a large number of demented elderly in the participating service stations. Because those suffering from dementia could not reply to the mental scale questions, we needed to exclude them from the object of this research. As for home rehabilitation, various stations justified users' refusal to participate in the study, alleging that many users already received home rehabilitation. This explanation, however, is in contradiction with the above mentioned reports.<sup>1,3,6</sup> This may be because (1) rehabilitation resources by area are different and not lacking in Aichi prefecture,<sup>4</sup> (2) the number of rehabilitation sessions per person may be small, and (3) nurses give home rehabilitations instead of physical therapists and occupational therapists.<sup>6</sup>

The baseline characteristics of the subjects in the HMG and the RCG were matched. This result supports the validity of the outcome measures in this study because the mental and physical state of the elderly is related to their social support.<sup>27</sup> However, we could not match the baseline outcome measurements between the two groups at the time of the allocation because this study did not accept enough participants to match the baseline outcome measurements at a time.

We should have excluded the provinces of rehabilitation, acupuncture and moxibustion from the study protocol to examine the effects of home massage accurately. In Japan, home massage programmes usually consist of medical massage and rehabilitation by a licenced massage practitioner. Some massage practitioners have a licence to practise acupuncture and moxibustion. According to some studies, home rehabilitation by physical therapists and/or occupational therapists may have an effect on ADL,<sup>28,29</sup> while acupuncture and moxibustion may have an effect on ADL and depressive mood.<sup>30,31</sup> As a result of a conference with the Massage Association, we concluded that rehabilitation could not be separated from home massage because rehabilitation, acupuncture and moxibustion are widely used in conjunction with massage in Japan.

### Effectiveness

A few studies indicate a significant improvement in ADL by three-month rehabilitation in the chronic stage.<sup>28,32</sup> To our knowledge, this is the first study investigating the effect of home massage rehabilitation therapy on ADL. We believe that this study is valuable in planning additional trials to assess the benefits of home massage rehabilitation therapy as an efficient substitute for hospital and/or home rehabilitation in the chronic stage.

However, the findings of the study may suggest that home massage rehabilitation therapy does not have a positive effect on the bed-ridden elderly in terms of ADL in the chronic stage. There are two possible reasons for this result: the first is that the three-month study period was too short to allow for the detection of significant differences. The second is that home massage rehabilitation alone may not trigger improvements in ADL. This result suggests that we need to appropriately combine home massage with other types of Western medical care services such as home nursing visits.<sup>31,33</sup>

Geriatric rehabilitation aims at the improvement of QOL in addition to higher ADL.<sup>34</sup> Massage has documented mental benefits.<sup>7,8,16,35</sup> However, we detected no changes in Subjective Satisfaction and Refreshment Scale scores, Apathy Scale scores and SDS in this study. These three scales may not match the study design because it is difficult to make an accurate assessment of QOL. We should also take it into consideration that more females were allocated to the HMG because there is a strong relation between depression and sex.<sup>27,36,37</sup> Additional research is needed for a more accurate appraisal.

**Table 4** Clinical course of all participants during six months

Group	Clinical course (illness)	n
HMG	Unknown	2
	Hospitalization	2
	Death (cerebral infarction)	1
RCG	Unknown	5
	Bad condition	2
	Hospitalizaion	6
	Death (cerebral infarction)	2

HMG, home massage rehabilitation therapy group; RCG, routine care group.

### Clinical messages

- Recently, the demand for massage therapy as a useful adjunct to medical treatment has been on the rise.
- For the bed-ridden elderly, home massage rehabilitation therapy is feasible but has not been shown to be effective.
- Additional large-scale studies would be required to give scientific evidence.

Safety is an important consideration in the provision of alternative medicine.<sup>12</sup> In our study, none of the HMG and four of the RCG were hospitalized and therefore excluded from the research. Furthermore, six months after the start of our research, a follow-up survey of study participants was conducted. We did not detect any serious complications in HMG when comparing our findings at six months. The results of our follow-up survey are detailed in Table 4. However, we need additional research to prove the safety of home massage accurately.

### Conclusion

We conducted a pilot study to investigate the effectiveness of home massage rehabilitation therapy. We concluded that this study did not suggest that home massage rehabilitation therapy was mentally and physically beneficial to the disabled at-home elderly. We need to conduct additional large-scale studies to give better evidence.

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### References

- 1 Kinjo T, Okajima Y. The relationship between community rehabilitation services and home care support system. *Hiroshima Kenritsu Hoken Fukushi Tandai Kiyo* 1997; 3: 1-9.
- 2 Ueda T, Hashimoto M, Goto H *et al.* Correlates associated with desire by caregivers to transfer elderly from home care to institutions. *Jpn J Public Health* 1993; 40: 1101-10.
- 3 Ohmine S, Kimura Y, Hachisuka K. Effect of out-patient physical therapy for stroke patients. *Rigaku Ryoho* 2000; 27: 306-10.
- 4 Miyatake G. Have the principle of the long-term care insurance system been achieved? In: Iryo Keizai Kikaku eds. *Iryo Hakusho 2001*. Tokyo: Nihon Kikaku, 2001: 91-105 (in Japanese).
- 5 Ishizawa M, Hama K, Sugita I. The research on the actual condition of the home visit rehabilitation in the medical institutions in Nagano prefecture. *Rigaku Ryoho Kenkyu Nagano* 2001; 29: 44-45 (in Japanese).
- 6 Ueno K. Special feature coping with 5 subjects of home rehabilitation. *Community Care* 2000; 2: 34-35 (in Japanese).
- 7 Smith MC, Stallings MA, Mariner S *et al.* Benefits of massage therapy for hospitalized patients: a descriptive and qualitative evaluation. *Altern Ther* 1999; 5: 64-71.
- 8 Serizawa K. *Theory and exercise of massage*. Tokyo: Ishiyakushuppan, 1969 (in Japanese).
- 9 Lee ACC, Kemper KJ. Practice patterns of massage therapists. *J Altern Complement Med* 2000; 6: 527-29.
- 10 Wood MJ, Stewart RL, Merry H *et al.* Use of complementary and alternative medical therapies in patients with cardiovascular disease. *Am Heart J* 2003; 145: 806-12.
- 11 Nishimura H. Actual condition of the home massage under the long-term care insurance. *Ido no Nippon* 2001; 683: 176-80 (in Japanese).
- 12 Cherkin DC, Sherman KJ, Deyo RA *et al.* A review of the evidence for the effectiveness, safety, and cost of acupuncture, massage therapy, and spinal manipulation for back pain. *Ann Intern Med* 2003; 138: 898-906.
- 13 Takebayashi N, Nakai Y. The social background of complementary and alternative medicine. *Terminal Care* 2000; 10: 333-36 (in Japanese).
- 14 Lee SI, Khang YH, Lee MS *et al.* Knowledge of attitudes toward, and experience of complementary and alternative medicine in western medicine-and oriental medicine-trained physicians in Korea. *Am J Public Health* 2002; 92: 1994-2000.

## 8 Y Hirakawa et al.

- 15 Ando F, Iguchi A. Diseases and bed-ridden condition. *Gerontology* 1997; 9: 401–409 (in Japanese).
- 16 Teshima M. Massage and therapeutic touch. *Terminal Care* 2000; 10: 361–63 (in Japanese).
- 17 Taylor AG, Galper DI, Taylor P et al. Effect of adjunctive Swedish massage and vibration therapy on short-term postoperative outcomes: a randomized, controlled trial. *J Altern Complement Med* 2003; 9: 77–89.
- 18 Farr T, Nottle C, Nosaka K et al. The effect of therapeutic massage on delayed onset muscle soreness and muscle function following downhill walking. *J Sci Med Sport* 2002; 5: 297–306.
- 19 Weinrich SP, Winrich MC. The effect of massage on pain in cancer patients. *Appl Nurs Res* 3 1990; 4: 140–45.
- 20 Meek SS. Effects of slow stroke back massage on relaxation in hospice clients. *Image-J Nurs Scholarsh* 1993; 25: 17–21.
- 21 Ferrell-Torry AT, Click OJ. The use of therapeutic massage as a nursing intervention to modify anxiety and the perception of cancer pain. *Cancer Nurs* 1993; 16: 93–101.
- 22 Wade DT. *Measurement in neurological rehabilitation*. Oxford: Oxford University Press, 1992: 175–78.
- 23 Kohashi N, Kumon Y, Iida N. Effect of Sermion (nicergoline) on aged stroke patients in quality of life (QOL) and activity of daily living (ADL). *Shinyaku to Rinsyo* 1996; 45: 1347–54 (in Japanese).
- 24 Okada K, Kobayashi S, Aoki K et al. Assessment of motivational loss in poststroke patients using the Japanese version of Starkstein's apathy scale. *Jpn J Stroke* 1998; 20: 318–23 (in Japanese).
- 25 Zung WWK. A self-rating depression scale. *Arch Gen Psychiatry* 1965; 12: 63–70.
- 26 Tsuboi A, Arai M, Matsuwaka T. Effects of sitting training, during visiting rehabilitation for the bed-ridden elderly. *Sagyō Ryōhō* 2001; 20: 36–44.
- 27 Harada S, Tsai SC, Sakihara S et al. The relationship between social support with depressive symptoms and life satisfaction among the elderly in a rural community. *Ryūkyū Med J* 2001; 20: 61–66.
- 28 Koch LV, Holmqvist LW, Kostulas V et al. A randomized controlled trial of rehabilitation at home after stroke in southwest Stockholm: outcome at six months. *Scand J Rehabil Med* 2000; 32: 80–86.
- 29 Crotty M, Kittel A, Hayball N. Home rehabilitation for older adults with fractured hips: How many will take part? *J Qual Clin Pract* 2000; 20: 65–68.
- 30 Matsumoto T, Terasawa S. Influence of acupuncture and moxibustion on QOL of the elderly living in nursing home and care house. *Jpn J Geriatr* 2001; 38: 205–11.
- 31 Washio M, Takasugi S, Arai Y. Effects of acupuncture therapy on low back pain and/or knee pain in elderly patients. *Jpn J Geriatr* 2001; 38: 523–27.
- 32 Katoh Y. Rehabilitation approaches to CVA from the acute phase. *Jpn J Geriatr* 2003; 40: 329–31.
- 33 Imanishi J, Watanabe S. The definition of alternative medicine. In: Imanishi J ed. *New trend in complementary and alternative medicine*. Tokyo: Ishiyaku Publishers, 2000: 1–6.
- 34 Chino N. Geriatric rehabilitation. *Jpn J Geriatr* 2002; 39: 507–508.
- 35 Dawson P, Kontos P. Back massage can reduce anxiety of elderly residents in long term care institutions. *Perspectives Fall* 1998; 22: 27.
- 36 Maki N, Ikeda M, Hokoishi K et al. Effect of demographic factors on geriatric depression scale(GDS) in healthy older adults. *Ronen Seishin Igakkai Zasshi* 2001; 12: 795–99 (in Japanese).
- 37 Nishimura R. Consideration on the relationship between depression in elderly people and psychosocial factors. *Hiroshima J Med Sci* 1999; 52: 218–21.

## 6) 「高齢者の終末期の医療およびケア」に関する 日本老年医学会の「立場表明」

植村 和正

Key words：高齢者，終末期医療，立場表明，倫理委員会，日本老年医学会

(日老医誌 2004；41：45-47)

### はじめに

日本老年医学会では平成10年9月より倫理委員会が発足し，老年医療分野における終末期医療に関する倫理的諸問題について議論が始まった。第一回の倫理委員会で浮き彫りになった問題点は，①高齢者への差別，いわゆるエイジズム，②高齢患者の自己決定，③家族・介護者の意向，④技術的な問題，⑤終末期医療および看護教育，⑥医療経済，⑦医療過誤などの法律問題，であった。倫理委員会では，以上の諸問題に対して日本老年医学会の「立場表明」を作成する方向で討議を進めた。その目的は，「すべての人が有する最善の医療を受ける権利を擁護・推進する」ことにある。

### 「立場表明」発表までの経緯

平成13年6月の日本老年医学会学術集会で「高齢者の終末期の医療およびケア」に関する日本老年医学科会の「立場表明」が表明されたが，この間，倫理委員会は5回開催されている。また，最初の倫理委員会案の作成から「立場表明」公表までに以下のプロセスを経た。

- ①平成11年9月の「老年医学」市民公開講演会における意見聴取
- ②平成12年6月の日本老年医学会学術集会で討議
- ③以上の議論を踏まえ，修正を加えた「立場表明案」に対する，日本老年医学会の学術評議員全員へのアンケート調査
- ④アンケート結果を踏まえて倫理委員会での最終案作成

### 「高齢者の終末期の医療およびケア」に関する日本老年医学会の「立場表明」

#### 1. 基本的立場

「人の老化と死に向かい合う老人医療は，生命科学で得られた成果を基盤にした生命倫理を重視した全人医療であるべきである。」

立場—1—：高齢であることや自立能力が低下しているなどの理由により，適切な医療およびケアが受けられない差別に反対する。

(論拠) 適切な医療およびケアを受ける権利は侵すことのできない基本的人権である

立場—2—：高齢者の終末期の医療およびケアは，患者個々の価値観や思想・信仰を十分に尊重して行われなければならない。

(論拠) 病名や病態に関する情報開示が高齢者である，あるいは患者個々の価値観や思想・信仰の故に，不十分であってはならない。考えられる予後や「終末期の医療やケア」に伴って起こりうる病状経過についての話し合いと合意が必要である。話し合いでは患者が希望することを尊重すべきである。

立場—3—：終末期医療では，患者の生活の質(QOL)の維持・向上に最大限の配慮がなされるべきである。

(論拠) 患者のQOLを維持，向上するための医療やケアが終末期の医療およびケアの主体となるべきである。終末期の医療およびケアとは，「痛みやその他の身体的症状を和らげるのみならず，患者の心理的・精神的な要求を真摯に受けとめ，援助し，患者のQOLを向上させる医療およびケア」であると考えられる。

立場—4—：終末期の医療およびケアには，患者本人だけでなく家族などのケアも含まれる。

(論拠) 終末期の医療およびケアにおいて，患者の家族は重要な役割を担う。患者の病状を家族に説明するとともに，そのことにより生じた家族の悲しみを和らげる

表1 倫理委員会委員

委員長	井口 昭久	名古屋大学老年科教授
委員		
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顧問	高村 浩	高村法律事務所 弁護士

など、医療者は家族に対して積極的に支援する必要がある。ここで述べる「家族など」とは、家族、患者の友人や介護者など患者の終末期に関わる人たちのことを言う。

## 2. 技術的課題

立場—5—：終末期における医療およびケアは医学のみならず看護・介護、社会・心理など、幅広い領域を含む集学的医療およびケアである。

(論拠) 終末期において死にゆく患者を対象とした医療およびケアは集学的に実施されることが望ましい。集学的チームのメンバーには、医師、看護師、ソーシャルワーカー、介護サービスの担当者、リハビリテーションの担当者、臨床心理士、ボランティア、家族などが含まれる。各々チームのメンバーは、患者の死にゆく過程で持ち得る知識と技術のすべてを患者の必要に応じて提供すべきである。

立場—6—：終末期医療およびケアにおいて施行される医療処置は、患者への利益が医学的に保証されたものであるべきである。

(論拠) あらゆる医療処置やケアに関して、「得られる利益に関する科学的裏付け」の獲得、および「標準化」を目指す努力が継続されるべきと思われる。「標準化」は医師の「恣意性」を排除して、患者の「自律性」を保証することを目標としたものになるであろう。

立場—7—：患者の「尊厳」や「自律性」の尊重は、個々の文化的背景などに配慮すべきである。

(論拠) 日本人には、医療の専門家に対する従順性や自らの境遇に対する運命論的受容など、欧米文化とは異なる「死生観」を生み出した文化的背景がある。高齢者では、情報が開示されることを拒絶する場合すらある。

この様な背景を無視し、十分な援助の準備もない告知は単に死の通告に他ならない。

## 3. 教育的課題

立場—8—：終末期患者が最善の医療およびケアを受ける権利を保障するために、医療者は実践的な教育を受けるべきである。

(論拠) 終末期患者の症状の管理技術、介護技術、患者とのコミュニケーション技術等について実践的な教育がなされるべきである。

立場—9—：「終末期の医療およびケア」は、終末期患者のQOLの向上に役立つものであることを、国民が理解することが望まれる。そのためには国民に対しての「終末期の医療およびケア」および「死の教育」が必要である。

(論拠) これにより、「終末期の医療およびケア」が終末期患者の尊厳を損なうものではないことが理解されるであろう。

## 4. 医療制度的課題

立場—10—：あるべき「終末期の医療およびケア」の実現のためには、社会制度的支援が不可欠である。

(論拠) 包括点数による診療報酬請求体系等の現行の医療制度があるべき高齢者の「終末期の医療およびケア」の実現を阻んでいる側面がある。

## 5. 研究に関する課題

立場—11—：十分な資金提供のもとに、あるべき「終末期の医療およびケア」の実現を目指す研究の推進が必要である。

(論拠) 症状緩和に関する研究、高齢患者の「自律性」を重んじた「終末期の医療およびケア実現」の方策、QOLの客観的評価法、在宅終末期医療およびケアの研究、などが必要である。さらに、日本人の「死生観」に根差した社会・心理的研究が必要とされている。

## 6. 国民的合意/社会への公開に関する課題

立場—12—：終末期における医療やケア行為の是非を検証できるような、第三者をいれた「倫理委員会」を各医療機関に設置し議論を行うと同時に、そこでの議論を広く公開し国民の意見にも耳を傾けるシステムをつくるべきである。

## 7. 「立場表明」の位置づけ

立場—13—：この立場表明は過渡期的な意見表明であって、今後科学的な手法を用いた検討により、この立場表明の妥当性自体が検証されるべきものである。

(論拠) 現在の我が国における「高齢者の終末期の医療およびケア」を取り巻く課題には、単に医学的見地のみからでは結論の出せないものが多くある。日本老年医



学会は学術団体として、これらの諸課題に対する調査・研究を行い、その結果を国民に提示し、議論を喚起する責任を負っていると考える。日本老年医学会の「立場表明」の公表は、あるべき「高齢者の終末期の医療およびケア」を実現するための活動の第一歩であると考えている。

### 倫理委員会の今後の活動方針

以上、「立場表明」を概述したが、今後はこの「立場表明」を踏まえて、さらに理想的な終末期医療実現のための活動が求められる。今後の倫理委員会の活動方針について述べる。

#### 1. 高齢患者の自己決定実現に向けての活動

まずは、「インフォームド・コンセント」の現状把握から始めたい。最終的には「インフォームド・コンセント」のガイドライン作成を目指している。

#### 2. 終末期医療やケアの診療ガイドラインの作成に向けての活動

これがおそらく最も困難な活動になると考えられる。なぜなら、個別性の高い終末期医療において、一律の診療指針はときに患者の人権を侵しかねないからである。まずは、地道な実証的研究が必要となろう。具体的には、①高齢者終末期の症候、徴候の把握、②高齢患者への病状説明の現状把握、③実際に施行されている医療措置の把握、などがその対象となると考えられる。最終的には

疾患ごと、あるいは症候や徴候ごとの診療ガイドラインの作成に取り組めれば望ましいと考えている。

#### 3. 終末期医療やケアの教育の充実と改善に向けての活動

まずはやはり現状調査から始めるべきであろう。具体的には、終末期医療に関する教育カリキュラムの有無とその内容に関する調査を踏まえ、最終的には終末期医療・ケア教育のモデルカリキュラムの作成に向かいたい。

#### 4. 各医療機関の「倫理委員会」活動に対する支援に向けての活動

これも現状調査を先行させたいと考える。「倫理委員会」の設置状況、活動内容の調査に加えて、具体的事例の収集などがその対象となろう。高齢者の終末期医療に関する「倫理委員会」のネットワークが構築できれば望外の喜びである。

### 文 献

- 1) 社団法人日本老年医学会：「高齢者の終末期医療およびケア」に関する日本老年医学会の「立場表明」, 日老医誌 2001;38:582-583.
- 2) 日本老年医学会倫理委員会委員長井口昭久：「高齢者の終末期医療およびケア」に関する日本老年医学会の「立場表明」を表明することに至った経緯について, 日老医誌 2001;38:584-586.

## 高齢者のターミナルケア

End of life care for the elderly



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◎遠からず“死”が避けられない状態となり患者の身体的苦痛・精神的苦痛の除去が医療の主眼となるとき、これを“ターミナルケア”とよぶ。“ターミナルケア”の目的は、苦痛・苦悩の緩和により患者の QOL を維持・向上することにある。高齢者の“ターミナルケア”の特徴を考えるとすることは、高齢者に特徴的な“終末期”に対する適切なケアのあり方を考えるということである。高齢者の“終末期”に対しては特徴的なケアがありうるということではない。

**Key word** : ターミナルケア, 高齢者, 終末期の定義, 自己決定

### 高齢者における終末期とは

“不治”かつ“末期”の状態が“終末期”と定義されるが、“不治”, すなわち非可逆的進行性の疾患に対して根治が不可能な状態は医学的に定義しやすい。一方、“末期”という用語は時間概念を含み、一般的に定義が困難である。現在罹患している疾患で遠からず死亡すると認められた時点から“終末期”ということが出来るが、時間的にはおおよそ6カ月かそれ以内とすることが多い<sup>1)</sup>。

以上が一般的な“終末期”の定義であるが、これはおおよそ非高齢者の悪性腫瘍を想定してのものであり、高齢者の場合は具体的定義がさらに困難でいまだ確立されたものはない。このことを受けて現在、終末期ケア、とくに高齢者の終末期ケアに関してはターミナルケアという用語を使用せず、“End-of-life Care(エンドオブライフケア)”という表現を使用することもある。さらには日本老年医学会は終末期の定義から時間概念を省略し、「病状が不可逆的かつ進行性で、その時代に可能な最善の治療により病状の好転や進行の阻止が期待できなくなり、近い将来の死が不可避となった状

態」と“終末期”を定義した(表1)<sup>2)</sup>。本稿では表題のようにターミナルケアという用語を使用する。

### 高齢者のターミナルケアの特徴

#### 1. 高齢者の悪性腫瘍の場合

悪性腫瘍に対するあらゆる根治療法(手術, 放射線, 化学療法)が無効で、放置すれば“死”に至る状態となった時点が“終末期”とすれば、これを判断することは困難ではない。しかし、高齢者の場合は悪性腫瘍の進行速度が非常に緩やかで“終末期”が6カ月を優に超える場合も珍しくない。また、経過が長くなれば、この間に肺炎や心不全、脳卒中など他の急性疾患に罹患し死亡することも多くなり、“死”に至る過程を予測することは非高齢者よりもかなり困難である。

#### 2. 慢性疾患での“終末期”

透析療法が拒否された末期の腎不全、慢性閉塞性肺疾患、治療に不応性の重症心不全、高齢がゆえに手術不能な脳出血やくも膜下出血などが該当する。末期の腎不全や致死的な脳出血の場合は予後(余命)の判断は比較的容易であるが、慢性の心

表 1 日本老年医学会による“終末期”の定義

<p><b>“立場表明”を出す目的</b></p> <p>わが国に生活するすべての人は人生の最終局面である“死”を迎える際に、個々の価値観や思想・信仰を十分に尊重した最善の医療を受ける権利を有する。最善の医療とは単に医学的な知識・技術のみではなく、他の自然科学や人文・社会科学を含めたこの国のすべての知的・文化的成果を還元した医療であると思われる。日本老年医学会はすべての人がこの権利を有すると考え、この権利を擁護・推進する目的で“高齢者の終末期の医療およびケア”に関する日本老年医学会の“立場表明”を表明する。</p>
<p><b>“立場表明”における定義</b></p> <p>“立場表明”で述べる“終末期”とは、「病状が不可逆的かつ進行性で、その時代に可能な最善の治療により病状の好転や進行の阻止が期待できなくなり、近い将来の死が不可避となった状態」とする。</p> <p>〔論拠〕高齢者は“終末期”にあると判断されても、わが国では余命を予測するための医学的成績の集積が現状では不十分であり、余命の予測が困難であるため、“終末期”の定義に具体的な期間の規定を設けなかった。</p> <p>“高齢者の終末期”の定義に関しては現在ではこのような曖昧なものであるが、“悪性腫瘍の終末期”、“脳卒中の終末期”、“痴呆疾患の終末期”、“呼吸不全の終末期”など、高齢者に多く不可逆的・進行性の過程をたどることの多い個別疾患ごとの検討が日本老年医学会の今後の課題となるであろう。</p> <p>また、高齢者が心身ともに個別性が高いことから年齢規定が不適切だと思われるので、“高齢者”に関して暦年齢による規定を行わなかった。</p>

肺疾患の場合は確実に“死”に向かいながらもこの間に急性代償不全のエピソードを繰り返していくが、どのエピソードも高齢者には潜在的に致死性であるので、正確な“死期”の判断は非常に難しい。

### 3. いわゆる老衰死

脳卒中などの疾患を契機に徐々に精神・身体機能が低下・衰弱して全身介助状態に至り、肺炎や心不全を引き起こしながら最終的に“死”に至る例がある。この経過は全体としてみれば特定の疾患や臓器不全によるものというより個体全体の“老化”の結果というべきものである。寝たきり・全面介助状態に至ると、患者の“人権”や“尊厳”が脅かされる可能性が高くなるので、この状態に至った“老衰”は“終末期”に準じて考えるべきだと主張が存在する<sup>3)</sup>。この場合も期間としては6カ月を超えることが少ない。

このような“老衰”の過程で生じる“摂食不能”を放置すれば“死”に至るが、この“老衰死”は“脱水死”であり、通常苦しみは少なく、死亡までの期間も短く、治療による苦痛もない、ある意味で受け入れやすい死に方といえる。ヨーロッパ諸国ではこのような場合に人工栄養を施さないで安らかに“死なす”ことが社会的合意となっているようである<sup>4)</sup>。しかし、わが国ではこのような場合に補液な

どの医療処置を施さない例はきわめて少ない。それは、ひとつにはこの場合の“摂食不能”が“不可逆的”であると判断することが困難だからである。“老衰”の経過中に生じる“摂食不能”は肺炎などの急性疾患が原因のことが多く、これを治療すれば摂食可能となる場合が少なくないからである<sup>4)</sup>。

もうひとつ大事な点は、ヨーロッパ諸国と異なり日本ではこのような場合の医療措置に対する国民的合意が成立していないことである。一般国民を対象にしたアンケートによれば、たとえ植物状態に陥ったとしても人工栄養などの延命処置を希望するものが少数ながら存在し、しかも高齢者ほどその比率が増加する<sup>5)</sup>。医療における“自己決定権”の行使が、慣習としても制度としても成熟しているとはいえない日本社会においては、“老衰”の過程での“終末期”の判断は非常に難しい。

### 4. 痴呆の“終末期”

痴呆が高度になると身体活動は著しく低下し摂食量も減少する。他者とのコミュニケーションもなくなり、食事も受け付けなくなり、最終的には“老衰”の末期と同様の状態に至る。かりに全面介助状態になった時点からを“終末期”とすれば、この場合も6カ月を超えることは珍しくない。

以上述べたように、“ターミナルケア”、とくに

高齢者のそれを正確に定義するには非常な困難を伴い、具体的に確立されたあり方は皆無といってもよい。このような観点から、高齢者終末期医療のあり方を提言したアメリカ老年医学会は、“終末期”患者の代りに“死にゆく人びと(dying patient)”という用語を用いている<sup>6)</sup>。

## ターミナルケアとは

遠からず“死”が避けられない状態となり患者の身体的苦痛・精神的苦痛の除去が医療の主眼となる時、これを“ターミナルケア”とよぶ。“ターミナルケア”の目的は苦痛・苦悩の緩和により患者のQOLを維持・向上することにある。だからといって“終末期”に発生した治癒可能な急性疾患をすべて放置することではない。治療すればふたたび苦痛のない時間がある程度予測されるならば、当然に治療されねばならない。

“ターミナルケア”においてQOLの視点はとくに重要である。残された時間をどのような状態ですごすことが有意義であるかは、患者個々の価値観によるところが大きい。患者の選択が保障されるためには適切なインフォームドコンセントが必要がある。そのうえで何の束縛もない自由意思で下されるのが“自己決定”である。

## 高齢者の“ターミナルケア”とは

高齢者の“ターミナルケア”の特徴を考えるとすることは、高齢者に特徴的な“終末期”に対する適切な医療のあり方を考えるということである<sup>6)</sup>。高齢者の“終末期”に対しては特徴的な医療がありうるということではない。この点を軽率に誤解すると、高齢者は予想される余命が短いので、非高齢者の“終末期”とは質的に異なる医療が許される、という誤りを冒す危険がある。これはエイジズム(年齢による差別)とよばれ、最近過少医療の問題として取り上げられることがある。適切な医療により救われる可能性がある高齢者が、“高齢”であるという理由で放置されてよいはずがない。

## “ターミナルケア”における死の迎え方の自己決定

さきほどもすこし触れたが、患者が自己決定を

する場合には、決定するために必要な事柄についての知識を事前に求めて、よく理解していることが前提となる。わが国ではこの前提条件が満足させられていなかったり、自己決定をするべき本人自身以外の者が決定してしまうことが少なくない。たとえ患者の病気が悪性腫瘍の末期と診断された場合でも、患者本人が自分が受けたいと思う治療法を選択するためには、医師がその患者に、患者の病状ばかりでなく、いろいろの治療法の内容や、それぞれの治療法の効果や副作用などの危険性を比較できるようにわかりやすく説明をする必要がある。そうでないと患者はどの治療法を選択することができない。そのうえでその治療を医師が自分に実施することについての同意を医師に与えることもできない。この手続きがとられなければ、インフォームドコンセントは実施できない<sup>7)</sup>。ただこの前提を維持することが、実は高齢者の終末期においては困難なことが多い。前に述べたように慢性疾患の“終末期”、“老衰死”、そして痴呆の“終末期”などにおいては、患者本人の自由意志を確認することが事実上不可能なのである。そのため、患者の死の迎え方について事前の自己決定の問題が最近一般にも注目されつつある。

### 1. リビングウィル

アメリカでは1976年に“カリフォルニア州自然死法”が制定されて「成人が末期状態になったときに、生命維持装置を中止するか取り外すように医師に対して文書をもって指示する書面を作成する権利をカリフォルニア州民に認める」と定めた。リビングウィルとよばれるこの文書を書いておく権利を認める法律を世界ではじめて法制化したのである。その後、アメリカでは1991年PSDAによって連邦法でも同様の権利を認め、全米で同様の権利が認められた<sup>8)</sup>。ただしわが国では法制化されていない。

### 2. 心肺蘇生拒否の指示

脳死状態の際に心肺蘇生術を拒否する指示を前もって医師にしておく、医師は患者の診療記録簿の表面に“DNR order”(do not resuscitate order: 心肺蘇生術拒否指示)と表記し、その指示に従うことで、患者の心肺蘇生拒否の意思が保障される。わが国では法制化されていない。