

we thought that BNP reflected the degree of seriousness of CHF as well as NYHA functional class did.

With regard to physiological outcomes, it was previously reported that peak $\dot{V}O_2$ and $\dot{V}E/\dot{V}CO_2$ slope vary inversely, and both are related to symptom scores and prognosis²⁰. Itoh *et al.*²¹ previously reported that peak $\dot{V}O_2$ is expressed as a percentage of predicted values determined. As a result, % peak $\dot{V}O_2$ decreases significantly with increasing severity of disease, or, in other words, peak $\dot{V}O_2$ decreases as NYHA functional class increases. In the present study, although LVEF of patients did not differ between NYHA functional class groups, peak $\dot{V}O_2$ decreased as NYHA functional class increased. This finding from our study is consistent with those of earlier studies²¹.

A recent study also reported that patients with CHF breathe more often during exercise than do controls, resulting in an increase in $\dot{V}E/\dot{V}CO_2$ slope²². In the present study, the $\dot{V}E/\dot{V}CO_2$ slope increased as NYHA functional class increased. The increased $\dot{V}E/\dot{V}CO_2$ slope must therefore be a result of other mechanisms²². Ventilation perfusion mismatch, impaired diffusion of metabolic gases, respiratory muscle weakness, and heightened sensitivity of peripheral receptors have all been postulated as possible causes²². In this way, physiological outcomes such as peak $\dot{V}O_2$ and $\dot{V}E/\dot{V}CO_2$ slope appeared to differentiate clearly between different grades of disease severity, as measured by NYHA functional class.

With regard to another important outcome, indices of HRQOL also decreased with NYHA functional class. All aspects of HRQOL were dramatically reduced in NYHA class I, II, and III patients, reflecting the severe impact of CHF on daily life, even though the patients were in a compensated stage and in an ambulatory setting. This also applied to another HRQOL instrument, the Nottingham Health Profile (NHP)²³, and suggested that when using the aforementioned measures, improvements in HRQOL may also reflect improved NYHA functional class. Indeed, quality of life, as reflected by the NHP, has been shown to improve, as has NYHA functional class, after heart transplantation²³. These data imply that HRQOL may be especially relevant in CHF, in which NYHA functional class is of prime importance.

In addition to NYHA functional class, more objective indices of functional capacity such as the 6-minute walk test also showed some relation to quality of life²⁴. However, Steptoe *et al.*⁶ found no univariate association between exercise capacity and quality of life in patients with mild to moderate CHF. In the present study, we also were not able to clarify this point. This raises the question as to which other predictors besides the most obvious prognostic somatic variables in CHF patients are important. Future trials are needed to evaluate the predictors of prognosis and/or mortality in patients with CHF.

Compared with the normal Japanese population, our CHF patients showed a global reduction in HRQOL as measured in 7 of the SF-36 subscales. Although the most pronounced loss of HRQOL was observed in the domain of role limitation because of physical problems, SF-36 subscales scores related to mental status such as social functioning and role-emotional were also low.

In apparently asymptomatic patients with left ventricular dysfunction, the SF-36 scores revealed significant decreases in the scales representing somatic physiological and mental status. In other words, poor HRQOL might be indicated not only by scores relating to physical but also mental state. The lack of association between LVEF and HRQOL is in total agreement with findings of previous studies²⁵⁻²⁶.

In addition to decrease in physiological outcomes such as peak $\dot{V}O_2$, one could speculate that these results reflect the effect of CHF on the central nervous system^{24,27}. Changes in central neurohumoral regulation systems or diminished central perfusion might impair cognitive capacity and trigger a latent vulnerability to depressive disorders^{24,27}.

Interestingly, with regard to the SF-36 bodily pain subscale score, we felt that improvement in this score was unrelated to bodily pain per se because CHF patients were not experiencing chest pain. For example, after the onset of AMI, patients may interpret the SF-36 bodily pain subscales as referring to chest pain. However, only 24% of patients in the present study had a previous MI. The possibility exists in the present study that CHF patients did not influence the SF-36 bodily pain subscale score. Therefore, we surmised that the bodily pain subscale may not be appropriate for the evaluation of patients with CHF.

To the best of our knowledge, Mitani *et al.*²⁸ are the only other group to have evaluated HRQOL in Japanese CHF patients with the SF-36 health survey. In their study, although 91 patients with CHF had very poor HRQOL and overall reported bodily pain, their patients' bodily pain scores were lower than those of the patients in our study. This discrepancy may be related to differences in patient characteristics. A possible reason may be that a higher percentage of CHF patients in their study had ischemic heart disease. Although our study patients included mainly those with cardiomyopathy, valvular heart disease, hypertensive heart disease, and atrial fibrillation, only 24% of patients had a previous myocardial infarction. In their study, 57% of CHF patients had ischemic heart disease. This may account for the difference in HRQOL-related findings between the present study and those of Mitani *et al.*

Recently, Tamura *et al.*²⁹ developed a disease-specific quality of life measure in patients with CHF. They suggested that a disease-specific quality of life questionnaire is applicable to the evaluation of HRQOL in patients with CHF. We believe that both the SF-36 and

disease-specific quality of life questionnaires may be needed to evaluate HRQOL in future trials.

There were several limitations in the present study. First, the present study comprised a small sample, and thus it was not possible to determine what factors might predict reduced HRQOL. We did not ascertain the reasons for impaired HRQOL. Other conditions, such as hip pain, cancer, or depression, for example, may also result in lower HRQOL scores. Therefore, further studies are needed to investigate the relation between HRQOL and other factors.

Second might be the cross-sectional design of the study. The main thrust of the present study was to assess the differences in degree of illness in relation to physiological outcome and HRQOL assessed at a particular time. Nevertheless, it would be highly desirable to document longitudinal change in physiological outcome and HRQOL in patients with CHF. HRQOL and disease-specific quality of life questionnaires should be used in future studies to evaluate not only the effect of exercise performance but mental status as it relates to HRQOL over the long term after CR.

Finally, in the present study, although differences in physiological outcomes associate with NYHA functional classes were determined, we did not directly measure leisure-time physical activity. A previous study has shown that leisure-time physical activity influences HRQOL positively³⁰. A recent review also indicated that an increased level of physical activity generally, although not always, favorably affects quality of life³¹. Therefore, future trials are needed to evaluate the relation between physical activity and HRQOL in patients with CHF.

Conclusion

We found in patients with CHF that as NYHA functional class increased, peak $\dot{V}O_2$ and almost all SF-36 subscale scores decreased, whereas $\dot{V}E/\dot{V}CO_2$ slope increased. NYHA functional class, but not LVEF, appears to be related to HRQOL. Thus, in patients with CHF, not only objective physiological outcomes but also HRQOL decreased as NYHA functional class increased. In addition, all SF-36 subscale scores except that for bodily pain were greatly lower when compared to those of the normal Japanese population. Future trials will need to evaluate the effect of CR for longitudinal settings and for longer periods; long-term follow-up will be required to evaluate whether these benefits continue over time.

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Age-related Differences in the Delivery of Cardiac Management to Women Versus Men With Acute Myocardial Infarction in Japan

Tokai Acute Myocardial Infarction Study: TAMIS

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SUMMARY

It is of concern that women are more likely to undergo fewer diagnostic tests and receive less treatment for acute myocardial infarction (AMI) than men. However, it is still unclear whether gender differences exist according to age groups. Therefore, we studied the influence of gender on the delivery of cardiac management according to two age groups (< 65, ≥ 65) in Japan. Data from the Tokai Acute Myocardial Infarction Study (TAMIS) sample were used. This is a retrospective study of all consecutive patients admitted to the 13 acute care hospitals in the Tokai region of Japan, which includes Aichi and Shizuoka Prefectures, with a diagnosis of AMI from 1995 to 1997. A total of 143 younger women, 822 younger men, 391 older women, and 611 older men were included. Information concerning patient demographics, in-hospital course, comorbid conditions, electrocardiography (ECG), ultrasound-echocardiography (UCG), treadmill test (TMT), coronary angiography (CAG), percutaneous transluminal coronary angioplasty (PTCA), coronary artery bypass graft (CABG), intra-aortic balloon pump (IABP), mechanical ventilation, and in-hospital or discharge medication (thrombolytics, vasopressors, aspirin, β -blockers, angiotensin-converting enzyme (ACE) inhibitors, calcium antagonists, nitrates) were collected. Among the young, after controlling for these baseline variables, women were significantly less likely to undergo PTCA compared to men (OR, 0.54, 95%CI, 0.35-0.82). After controlling for these baseline variables, only lipid-lowering therapy tended to be more frequent in women than in men among the elderly (OR, 2.79, 95%CI, 1.47-2.58). The findings suggest that younger women with AMI are less likely than younger men to undergo PTCA, and that older women with AMI are more likely to receive lipid-lowering therapy. (Int Heart J 2005; 46: 939-948)

Key words: Acute myocardial infarction (AMI), Gender, Age group, Percutaneous transluminal coronary angioplasty (PTCA), Lipid-lowering therapy

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CARDIOVASCULAR disease is a leading cause of death throughout the world, including in Japan, where Western-style diets are being increasingly adopted.^{1,2)} In Western countries, it is of concern that women are less likely to undergo acute myocardial infarction (AMI) diagnostic tests and treatments.^{1,3-5)} Some studies have shown this, while others have suggested that women receive similar degrees of diagnostic tests and treatments for AMI as men.^{1,2,4,6-10)} There is still a significant amount of controversy concerning this matter so it has been impossible to come to any definite conclusion. It remains unclear whether gender differences in these treatments exist.^{11,12)}

In addition, it has been suggested that the elderly with AMI are treated less aggressively than younger persons.^{1,13,14)} Therefore, we studied whether gender differences in AMI management are different between younger and older populations, as previously suggested by Montague, *et al.*¹⁵⁾

The purpose of this multihospital retrospective study was to study age-specific gender differences in the use of medications and the utilization of diagnostic and revascularization procedures among patients hospitalized for AMI.

METHODS

Study population: Data from the Tokai Acute Myocardial Infarction Study (TAMIS), a multihospital retrospective study in the Tokai region of Japan (Central Japan), were used. All of the study subjects were adult patients hospitalized due to a diagnosis of AMI at thirteen acute care hospitals between January 1995 and December 1997. Their diagnoses were confirmed by subsequent chart reviews. Patients admitted more than once with a diagnosis of AMI were included in the analysis. With regards to the recruitment of participant hospitals, we first selected the major hospitals which had an interchange of personnel with Nagoya University Hospital, where we are based. Second, we sent a prospectus about our research to the hospitals selected, 13 of which approved the study. The 13 hospitals were municipal or nonprofit general hospitals which were able to perform coronary angiography (CAG) and percutaneous coronary intervention (PTCA). Not all of the hospitals had a department of cardiovascular surgery or could conduct coronary artery bypass grafting (CABG) during the study period, however, we could not make identify the hospitals even by follow-up interview with the hospital staff in charge.

Data collection: We abstracted the baseline and procedural characteristics from detailed chart reviews which included both physician notes and nursing notes by physicians or skilled nurses educated to obtain medical records. The chart abstractors were blinded to the study hypothesis or anticipated study results. The questionnaire contained information on patient demographics, the in-hospital

course (length of stay, ICU/CCU transfer), comorbid conditions, clinical presentation (body mass index, body temperature, systolic arterial pressure, heart rate, chest pain, pulmonary edema, shock, bleeding, Killip class, ultrasound-echocardiogram (UCG), treadmill test (TMT), locations of MIs, and earlier admission activity of daily living (ADL)), procedural characteristics [CAG, PTCA, CABG, intra-aortic balloon pump (IABP), mechanical ventilation, time from onset to angiography, and in-hospital and discharge medication (thrombolytics, vasopressors, aspirin, β -blockers, angiotensin-converting enzyme (ACE) inhibitors, calcium antagonists, nitrates)]. A history of various comorbid conditions was recorded as present if it was documented in the medical charts. If no information

Table I. Baseline Characteristics of the Patients

	Group A (< 65)					Group B (\geq 65)				
	Women (n = 143)	%	Men (n = 822)	%	P value	Women (n = 391)	%	Men (n = 661)	%	P value
Age (mean \pm SD)	56.80		54.70		< 0.01	76.00		72.95		< 0.01
Body temperature (mean \pm SD)	36.20		36.20		NS	36.10		35.10		NS
Heart rate (beats/min, mean \pm SD)	83.50		80.46		NS	83.00		80.10		< 0.05
Systolic blood pressure (mmHg, mean \pm SD)	130.80		131.82		NS	127.00		127.90		NS
Killip class										
1	4	2.80	18	2.19	NS	7	1.79	7	1.06	NS
> 1	48	33.57	258	31.39	NS	198	50.64	268	40.54	< 0.01
Lodger	128	89.51	737	89.66	NS	323	82.61	596	90.17	< 0.01
Spouse	112	78.32	675	82.12	NS	179	45.78	542	82.00	< 0.01
Body mass index	24.01		23.81		NS	22		22.25		NS
Hypertension	71	49.65	275	33.45	< 0.01	181	46.29	241	36.46	< 0.01
Hypercholesterolemia	27	18.88	114	13.87	NS	32	8.18	46	6.96	NS
Diabetes	48	33.57	209	25.43	< 0.05	98	25.06	131	19.82	< 0.05
Previous angina	15	10.49	88	10.71	NS	58	14.83	118	17.85	NS
Previous heart failure	4	2.80	25	3.04	NS	35	8.95	36	5.45	< 0.05
Previous myocardial infarction	10	6.99	75	9.12	NS	32	8.18	86	13.01	< 0.05
Smoking	46	32.17	601	73.11	< 0.01	59	15.09	335	50.68	< 0.01
Arrhythmia	10	6.99	67	8.15	NS	47	12.02	68	10.29	NS
Renal failure	6	4.20	16	1.95	NS	4	1.02	23	3.48	< 0.05
Cerebrovascular disease	5	3.50	45	5.47	NS	52	13.30	88	13.31	NS
COPD	1	0.70	4	0.49	NS	0	0.00	12	1.82	< 0.01
Aortic aneurysm	2	1.40	7	0.85	NS	0	0.00	8	1.21	< 0.05
Peptic ulcer	4	2.80	83	10.10	< 0.01	11	2.81	74	11.20	< 0.01
Cancer	5	3.50	15	1.82	NS	27	6.91	37	5.60	NS
Allergy	11	7.69	53	6.45	NS	13	3.32	23	3.48	NS
Dementia	0	0.00	4	0.49	NS	12	3.07	10	1.51	NS
End of life stage	2	1.40	1	0.12	< 0.05	4	1.02	2	0.30	NS
Locations of MI										
Antero/septal	64	44.76	386	46.96	NS	178	45.52	299	45.23	NS
Lateral	11	7.69	47	5.72	NS	23	5.88	36	5.45	NS
Posterior	26	18.18	145	17.64	NS	50	12.79	115	17.40	< 0.05
Inferior	48	33.57	236	28.71	NS	124	31.71	205	31.01	NS
Subendocardial	1	0.70	11	1.34	NS	3	0.77	6	0.91	NS
Others	9	6.29	41	4.99	NS	21	5.37	38	5.75	NS
Independent ADL	137	95.80	809	98.42	< 0.05	356	91.05	621	93.95	NS
Chest pain	35	24.48	182	22.14	NS	81	20.72	164	24.81	NS
Shock	26	18.18	147	17.88	NS	109	27.88	131	19.82	< 0.01
Bleeding	17	11.89	115	13.99	NS	63	16.11	81	12.25	NS
Pulmonary edema (X-ray)	33	23.08	172	20.92	NS	143	36.57	203	30.71	NS

Group A indicates young group; Group B, old group; COPD, chronic obstructive pulmonary disease; MI, myocardial infarction; and ADL, activity of daily living.

was documented, then the comorbid condition was recorded as absent.

Statistical analysis: We compared the baseline and procedure characteristics and clinical outcomes between women and men according to two age groups (< 65, \geq 65). Statistical analysis was performed using the chi-square test for categorical variables and the unpaired t test for continuous variables. We also performed multiple logistic regression analysis to identify the independent association between gender and cardiac care according to the age group, after adjusting for other baseline and procedural factors that differed significantly between women and men. Univariate predictors of the cardiac care with a *P* value less than 0.05 could be used in the model. We present the results as odds ratios (OR) and 95% confidence intervals (CI). A *P* value less than 0.05 was considered statistically significant.

RESULTS

Baseline characteristics: A total of 143 younger women, 822 younger men, 391

Table II. Procedural Characteristics of the Patients

	Group A (< 65)					Group B (\geq 65)				
	Women (n = 143)	%	Men (n = 822)	%	<i>P</i> value	Women (n = 391)	%	Men (n = 661)	%	<i>P</i> value
Length of stay	31.12		27.93		NS	32.00		27.13		NS
Transfer to ICU/CCU	114	79.72	653	79.44	NS	299	76.47	521	78.82	NS
UCG	124	86.71	708	86.13	NS	338	86.45	578	87.44	NS
TMT	29	20.28	165	20.07	NS	40	10.23	97	14.67	< 0.05
CAG	134	93.71	789	95.99	NS	301	76.98	545	82.45	< 0.05
Time to CAG										
< 6	23	16.08	131	15.94	NS	54	13.81	99	14.98	NS
6-12	3	2.10	29	3.53		5	1.28	16	2.42	
> 12	18	12.59	59	7.18		36	9.21	47	7.11	
EF (% , mean \pm SD)	57.70		56.27		NS	59.50		55.73		NS
PTCA	87	60.84	628	76.40	< 0.01	215	54.99	404	61.12	NS
CABG	7	4.90	39	4.74	NS	16	4.09	36	5.45	NS
Thrombolytics	23	16.08	175	21.29	NS	53	13.55	108	16.34	NS
Vasopressor	49	34.27	254	30.90	NS	175	44.76	258	39.03	NS
IABP	21	14.69	127	15.45	NS	64	16.37	88	13.01	NS
Mechanical ventilation	16	11.19	79	9.61	NS	65	16.62	102	15.43	NS
Discharge medication										
Aspirin	102	71.33	527	64.11	NS	268	68.54	448	67.78	NS
β -Blocker	11	7.69	43	5.23	NS	14	3.58	18	2.72	NS
ACE inhibitors	48	33.57	330	40.15	NS	124	31.71	202	30.56	NS
Nitrates	57	39.86	314	38.20	NS	123	31.46	215	32.53	NS
Calcium channel blockers	73	51.05	385	46.84	NS	138	35.29	254	38.43	NS
Diuretics	19	13.29	75	9.12	NS	84	21.48	97	14.67	< 0.01
Antihyperlipidemics	25	17.48	102	12.41	NS	35	8.95	38	5.75	< 0.05

ICU/CCU indicates intensive care unit/coronary care unit; UCG, ultrasound-echocardiogram; TMT, treadmill test; CAG, coronary angiography; EF, ejection fraction; PTCA, percutaneous coronary intervention; CABG, coronary artery bypass graft; and IABP, intra-aortic balloon pump.

older women, and 611 older men were included in the analysis. Among the group under age 65 (the young group), the women were significantly older than the men (Table I). They were more likely to have a history of hypercholesterolemia or diabetes and to be in the end-of-life of all sorts of diseases, but they were less likely to have a history of smoking or peptic ulcer disease. Women were more likely to be independent with respect to their activities of daily living.

Among the elderly, the women were significantly older than the men. The initial heart rate was higher in women. Women were more likely to have signs of heart failure on presentation (Killip class > I, 50.6% versus 40.5%, respectively). They were more likely to have a history of hypercholesterolemia, diabetes or heart failure, but less likely to have a lodger, a spouse, a history of myocardial infarction, smoking, renal failure, or peptic ulcer disease. Women were more likely to develop cardiogenic shock and less likely to present with posterior infarction.

Procedural characteristics: Among the young, women stayed in hospital almost as long as men (Table II). They were less likely to undergo PTCA. Gender was not associated with the likelihood of receiving TMT or CAG. Among the elderly, women were less likely to receive TMT or CAG (Table IV). They were also less

Table III. Use of Medication, Diagnostic Test and Treatment for AMI Among Young Patients (Below 65) Among Women Versus Men

	Unadjusted OR	95%CI	Age adjusted OR	95%CI	Multivariable adjusted OR*	95%CI
Aspirin	1.39	0.94-2.06	1.41	0.95-2.08	1.51	0.98-2.31
β -Blocker	1.51	0.76-3.00	1.64	0.82-3.30	1.53	0.72-3.28
ACE inhibitors	0.75	0.52-1.10	0.73	0.50-1.07	0.79	0.52-1.21
Lipid lowering therapy	1.50	0.93-2.41	1.61	0.99-2.61	1.55	0.91-2.61
Nitroglycerin	1.07	0.75-1.54	1.05	0.73-1.52	1.14	0.76-1.71
Ca channel blocker	1.18	0.83-1.69	1.22	0.85-1.74	1.05	0.71-1.55
Diuretics	1.53	0.89-2.61	1.46	0.85-2.50	1.24	0.68-2.25
Vasopressor	1.17	0.80-1.71	1.09	0.74-1.59	1.02	0.67-1.55
Thrombolytics	0.73	0.45-1.18	0.74	0.46-1.20	0.75	0.44-1.29
IABP	0.91	0.55-1.53	0.88	0.52-1.48	0.78	0.43-1.41
Mechanical ventilation	1.16	0.65-2.05	1.08	0.61-1.92	0.90	0.47-1.71
CAG	0.59	0.27-1.26	0.61	0.28-1.31	0.60	0.25-1.46
PTCA	0.49	0.33-0.71	0.51	0.35-0.74	0.54	0.35-0.82
CABG	1.03	0.45-2.34	0.95	0.41-2.18	0.85	0.35-2.08
UCG	1.00	0.55-1.82	0.98	0.53-1.78	0.89	0.46-1.75
TMT	1.03	0.66-1.60	1.03	1.02-1.08	1.15	0.70-1.89

AMI indicates acute myocardial infarction; UCG, ultrasound-echocardiogram; TMT, treadmill test; CAG, coronary angiography; PTCA, percutaneous coronary intervention; CABG, coronary artery bypass graft; IABP, intra-aortic balloon pump; OR, odds ratio; and CI, confidence interval.

*Controlling for age, hypertension, diabetes, smoking, peptic ulcer, end-of life stage, and independence of activity of daily living.

Table IV. Use of Medication, Diagnostic Test and Treatment for AMI Among Old Patients (65 and Older) Among Women Versus Men

	Unadjusted OR	95%CI	Age adjusted OR	95%CI	Multivariable adjusted OR*	95%CI
Aspirin	1.04	0.80-1.36	1.03	0.78-1.35	0.92	0.65-1.31
β -Blocker	1.41	0.69-2.89	1.59	0.76-3.33	1.34	0.51-3.53
ACE inhibitors	1.06	0.81-1.39	1.18	0.89-1.56	1.20	0.83-1.74
Lipid lowering therapy	1.61	1.00-2.60	2.18	1.33-3.57	2.79	1.47-5.28
Nitroglycerin	0.96	0.73-1.25	0.99	0.76-1.31	1.22	0.85-1.77
Ca channel blocker	0.88	0.68-1.14	1.00	0.77-1.31	0.94	0.66-1.35
Diuretics	1.59	1.15-2.20	1.44	1.04-2.01	1.05	0.68-1.62
Vasopressor	1.24	0.96-1.60	1.14	0.88-1.48	0.84	0.56-1.25
Thrombolytics	0.78	0.54-1.11	0.86	0.59-1.24	0.96	0.60-1.55
IABP	1.24	0.86-1.77	1.42	0.98-2.05	1.21	0.71-2.06
Mechanical ventilation	1.06	0.76-1.50	1.10	0.78-1.57	0.70	0.41-1.20
CAG	0.69	0.51-0.95	1.10	0.77-1.55	1.35	0.83-2.20
PTCA	0.74	0.58-0.96	0.93	0.71-1.22	1.25	0.87-1.80
CABG	0.73	0.4-1.34	0.87	0.47-1.60	0.68	0.28-1.64
UCG	0.69	0.44-1.06	0.70	0.44-1.09	0.79	0.47-1.33
TMT	0.65	0.44-0.96	0.76	0.51-1.14	0.89	0.51-1.58

See Table III for abbreviations.

*Controlling for age, heart rate, Killip class, spouse, hypertension, diabetes, previous heart failure, previous myocardial infarction, smoking, renal failure, chronic obstructive pulmonary disease, aortic aneurysm, peptic ulcer, AMI location, and cardiogenic shock.

likely to receive PTCA, but not significantly. Women were more likely to receive therapy with diuretics or antihyperlipidemics during their hospital stay.

Multivariable analyses: Multiple regression analysis was carried out to more systematically examine the relations between gender and in-hospital management while controlling for differences in baseline variables, in which statistically significant differences were detected between women and men. Because we considered the presence of a lodger to be strongly correlated to the presence of a spouse, the presence of a lodger was not included in our regression models. The multivariable-adjusted results of in-hospital management are shown in Tables III and IV. Among the young, after controlling for these baseline variables, women were significantly less likely to receive PTCA than men (OR, 0.54, 95%CI, 0.35-0.82) (Table III). Among the elderly, women were likely to receive therapy with diuretics or antihyperlipidemics, and less likely to receive CAG, PTCA, or TMT before controlling for differences in the previously described variables (Table IV). After controlling, the differences disappeared, and only lipid-lowering therapy tended to be more frequent in women than in men (OR, 2.79, 95%CI, 1.47-2.58).

DISCUSSION

This large-scale retrospective study examined the influence of age and gender in Japan on the delivery of cardiac management in patients with acute myocardial infarction. We expected, on the basis of previous studies,^{2,9)} that differences in in-hospital management between women and men with AMI would be influenced by age, and divided the study subjects into two different age groups. In fact, our results suggested that there were age-specific gender differences in the in-hospital management of patients hospitalized with AMI in the Tokai region of Japan. Namely, our results indicated that lipid-lowering medications were used more frequently among elderly women, and that PTCAs were used less frequently among younger women. It was previously reported that women were more likely to receive lipid-lowering medications¹³⁾ and less likely to undergo PTCA^{1,11)} than men. Our results were also in accordance with those of previous studies, which have shown that women and men were different in their baseline backgrounds;^{1,3,16)} women are older, and more likely to have hypertension, diabetes mellitus, or previous heart failure, while men are more likely to have had a history of smoking or previous myocardial infarction.

With regards to lipid-lowering therapy, our findings suggested that older women were more likely to receive lipid-lowering therapy even after multivariable adjustment. Some previous studies have reported similar results as ours;¹³⁾ however, Bakler, *et al* suggested that women were less likely to receive lipid-lowering therapy.¹⁾ It is still unclear whether or not a difference in the incidence of lipid-lowering therapy between women and men exists. In addition, the reason why women were treated more with lipid-lowering therapy is unclear. However, the following explanation may be a good one as to why there is an overuse of lipid-lowering therapy among elderly women: compared to men, the number of women with hyperlipidemia increases dramatically after menopause. In addition, Yarzebski, *et al* pointed out that less women than men were having their serum cholesterol level measured.¹⁸⁾ Therefore, it is conceivable that older women were more likely to have been newly diagnosed with hyperlipidemia during their hospitalization, at which point they started receiving lipid-lowering therapy. In addition, it is possible that older women may be more shocked than older men upon learning they have high cholesterol levels, and that because of this, they request lipid-lowering therapy. Because there is, to our knowledge, no study to support this conjecture, additional study is needed to support the hypothesis that elderly women are shocked more frequently. Among the elderly only, the results of our study suggest that women are more likely to receive a diuretic, as some previous studies have suggested.^{1,16)} However, the difference in the incidence of diuretic treatment disappeared after adjustment for multivariables, including shock and

the Killip class, which were representative of the severity of the heart failure. This suggests that the more frequent occurrence of severe heart failure among women caused the more frequent administration of diuretics in women.¹⁶⁾

Our results do not suggest that women were less likely to undergo ECG or TMT. In addition, they also suggested that TMT was not performed frequently. Leslie, *et al* demonstrated that women may be less likely to undergo TMT, because this test, compared to CAG, cannot sufficiently predict ischemic events in women.²⁾ The underuse of TMT may no longer be problematic.

In our study, there were no gender differences in the incidences of CAG and CABG in both age groups after age and multivariable adjustment. However, with regards to PTCA, even after multivariable adjustment, women had undergone less PTCA than men in the younger population, though not in the older one. Because the rate of coronary angiography and time to coronary angiography is similar between young men and young women, the lower use of PTCA may be due to a higher prevalence of insignificant coronary stenoses in women.^{19,20)} Other reasons which may account for why women underwent less PTCA include failure on the part of the physician to offer it, or reluctance on the part of the women to consent to their physician's recommendations. Some researchers have suggested the following as concrete reasons:

- Female patients' lack of knowledge of AMI symptoms may cause a delay in their seeking medical assistance for those symptoms.²¹⁾
- Gender of physician - a male physician tends to treat a female patient less aggressively.²²⁾
- Gender difference in AMI symptoms - females complain of AMI symptoms such as chest pain even when AMI is absent.^{17,19,23-25)}
- Gender bias - women or minorities tend to be treated less aggressively by physicians.^{5,26)}
- Gender difference in socioeconomic status - women may have a lower economic status, and are more likely to hesitate undergoing an expensive treatment such as PTCA.^{12,19)}

Further studies are needed to prove these hypotheses.

Study limitations: There are several important limitations to this study. First, the sample size was not as large as that used in previous studies. Databases for the study of AMI in Japan are not available. Therefore, we had to build a database for our study by ourselves, by visiting the participating hospitals. However, the present study is valuable and contains many interesting findings. Presently, there is no national database in non-Western countries which can be compared with Western countries.³⁾ As mentioned above, some researchers have suggested that gender differences in AMI management may be caused by socioeconomic factors. Our results may be highly suggestive of this.

Second, we began collecting data in 2001, and spent over three years completing this data set. Therefore, it may have become too old to analyze. It is time-consuming to conduct chart reviews, and it is ethically problematic to have many examiners coming into hospitals and obtaining personal data, although we did obtain approval from the ethical committee at each hospital. We have also been conducting a prospective study (TAMIS-II) since 2001. TAMIS-II is investigating the same issues as TAMIS-I. We will be able to show temporal trends in AMI management by analyzing the results of TAMIS-II.

Third, our database does not always capture the full extent of the characteristics and clinical courses of the study subjects. Some physicians in the participating hospitals collected data together in their own hospitals; however, trained nurses to whom we gave a lecture on cardiovascular disease collected most of our dataset. Due to the lack of examiners, we should have secured personnel to regularly collect data. Although we trained the nurses and made sure that they could collect the data in practice, it is possible that the data collecting procedures varied among the hospitals depending on who was in charge of the data collection in each hospital, because not all trained nurses are familiar with medical data on circulatory illnesses.

Finally, although our intention was to construct a comprehensive questionnaire, there was a lot of missing laboratory data, such as the distribution of cholesterol levels, CK-MB, or ST elevation.

Conclusion: We conducted a retrospective study to investigate the age differences in the delivery of cardiac management to women versus men with acute myocardial infarction in Japan. The results suggest that there were age-specific gender differences in the in-hospital management of patients hospitalized with AMI. Younger women with AMI are less likely than younger men to receive PTCA. Older women with AMI are more likely to receive lipid-lowering therapy. Our study was limited due to the fact that the data collected was old and because of the small sample size. We intend to analyze our prospective study (TAMIS-II) to confirm the results obtained herein.

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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: Alternatively 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 receiving 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, 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 ± 4.51) at baseline was nonsignificantly lower ($p = 0.03$) than those of the RCG (11.44 ± 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, either mentally or 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 the number of bed-ridden patients who remain at home.^{1,2} 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.^{1,3-6} 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.^{7,8} Recently, the demand for massage therapy as a useful adjunct to medical treatment has been on the rise in the US.⁹⁻¹²

There is now a need for 'evidence-based alternative medicine' in addition to evidence-based medicine.^{7,10,13,14} Various countries, including the US, have encouraged research into the effects of alternative medicine.^{11,13,15} 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.^{7,16-21}

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. Staff 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 was 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.⁸ 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),²² Subjective Satisfaction and Refreshment Scale,²³ Apathy Scale^{3,24} and Self-rating Depression Scale (SDS).²⁵ 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 headings, 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 χ^2 test. Continuous data were 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 concerning participants' recruitment. Seventeen stations cooperated 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).

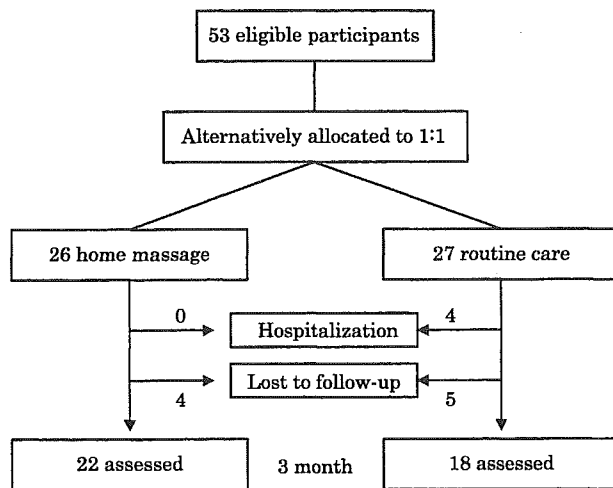


Figure 1 Flow diagram for the trial.

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, 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 ± 4.51) at baseline was nonsignificantly lower than that of the RCG (11.44 ± 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 ± 0.85 and 1.35 ± 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 χ^2 test. Continuous data were compared using the Mann-Whitney test.

Table 2 Outcome measurements of subjects at baseline

Variable	HMG (n = 22)	RCG (n = 18)	p-value
BI (mean ± SD) (95% CI)			
Total (0–20)	15.27 ± 4.51 (13.27–17.27)	11.44 ± 5.90 (8.51–14.38)	0.03
Feeding (0–2)	1.77 ± 0.53 (1.54–2.01)	1.56 ± 0.71 (1.21–1.91)	0.40
Bathing (0–1)	0.46 ± 0.51 (0.23–0.68)	0.22 ± 0.43 (0.01–0.43)	0.21
Grooming (0–1)	0.73 ± 0.46 (0.53–0.93)	0.61 ± 0.50 (0.36–0.86)	0.53
Dressing (0–2)	1.50 ± 0.67 (1.20–1.80)	0.94 ± 0.73 (0.58–1.31)	0.03
Bowel (0–2)	1.64 ± 0.58 (1.38–1.89)	1.50 ± 0.86 (1.07–1.93)	0.92
Bladder (0–2)	1.41 ± 0.67 (1.11–1.70)	1.44 ± 0.78 (1.05–1.83)	0.73
Toilet use (0–2)	1.64 ± 0.58 (1.38–1.89)	1.06 ± 0.73 (0.69–1.42)	0.02
Transfers (0–3)	2.55 ± 0.67 (2.25–2.84)	2.00 ± 0.97 (1.52–2.48)	0.09
Mobility (0–3)	2.50 ± 0.80 (2.14–2.86)	1.50 ± 1.25 (0.88–2.12)	0.01
Stairs (0–2)	1.09 ± 0.68 (0.79–1.39)	0.72 ± 0.75 (0.35–1.10)	0.14
Subjective Satisfaction Scale (mean ± SD) (95% CI)	0.90 ± 0.85 (0.50–1.30)	1.35 ± 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 to which group the participants were assigned. We enlisted each station to perform the evaluation because of a shortage of staff and the large quantity of settings. This may have biased

Table 3 Outcome measurements of subjects at three months

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

assessors' evaluation and limited the validity of the results. Bed-ridden people in our inclusive criteria are more prone to dementia.²⁶ 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.^{1,3,6} This may be because (1) rehabilitation resources by area are different and not lacking in Aichi prefecture,⁴ (2) the number of rehabilitation sessions per person may be small, and (3) nurses give home rehabilitations instead of physical therapists and occupational therapists.⁶

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.²⁷ 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,^{28,29} while acupuncture and moxibustion may have an effect on ADL and depressive mood.^{30,31} 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 of stroke patients by three-month rehabilitation in the chronic stage.^{28,32} 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.^{31,33}

Geriatric rehabilitation aims at the improvement of QOL in addition to higher ADL.³⁴ Massage has documented mental benefits.^{7,8,16,35} 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.^{27,36,37} Additional research is needed for a more accurate appraisal.

Table 4 Clinical course of all participants during six months

Group	Clinical course (illness)	<i>n</i>
HMG	Unknown	2
	Hospitalization	2
	Death (cerebral infarction)	1
RCG	Unknown	5
	Bad condition	2
	Hospitalization	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 increased.
- 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.¹² 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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