Association Between Unmet Needs for Medication Support and All-Cause Hospitalization in Community-Dwelling Disabled Elderly People

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OBJECTIVES: To clarify the association between unmet medication management need and 3-year mortality and hospitalization for community-dwelling older people with various levels of disabilities.

DESIGN: Prospective cohort study (the Nagoya Longitudinal Study for Frail Elderly).

SETTING: Community-based.

PARTICIPANTS: One thousand seven hundred seventy-two community-dwelling elderly subjects (611 men, 1,161 women).

MEASUREMENTS: Data included the clients' demographic characteristics, a rating for basic and instrumental activities of daily living (ADLs), number of prescribed medications and physician-diagnosed chronic diseases, medication adherence, ability to manage medication, and presence or absence of medication assistance. Cox proportional hazard models and the Kaplan-Meier method were used to assess the association between the medication management at baseline and mortality or hospitalization during a 3-year period.

RESULTS: Of 1,772 participants, 681 reported no difficulty with self-medication management, and 1,091 experienced difficulty with self-medication. Of participants with difficulty with self-medication management, 929 had medication assistance, and 162 did not. During a 3-year follow up, 424 participants died, and 758 were admitted to hospitals. The baseline data demonstrated that participants not receiving medication assistance were younger and had better ADL status and fewer comorbidities. Multivariate Cox regression models adjusting for potential confounders showed that the lack of assistance in those who needed medication assistance was associated with hospitalization but not mortality during the study period.

CONCLUSION: In community-dwelling disabled elderly people, lack of medication assistance in those needing medication support was associated with higher risk of hospitalization. J Am Geriatr Soc 56:881–886, 2008.

Key words: medication management; mortality; hospitalization; elderly; unmet need

Many community-living older people live without the help they need in performing not only basic activities of daily living (ADLs) but also instrumental ADL tasks (IADLs).[1,2] Prior studies have determined that living with unmet ADL needs is associated with poor clinical outcomes, including mortality, and greater use of primary, emergency, and acute healthcare services.[2-4] However, it remains unclear whether the unmet IADL needs may also lead to adverse outcomes for community-dwelling elderly people.

Of various tasks of IADL, medication management, including medication use, seems important for older people, because poor medication management skills seem to be involved in nonadherence to a medication regimen.[5-7] However, it remains unclear whether unmet medication management need is associated with poor outcome for community-dwelling older people with various levels of disabilities.

The present study examined whether unmet needed support for medication management was associated with poor clinical outcomes, including all-cause mortality and hospitalization, during a 3-year study period.

METHODS

Subjects

The present study employed baseline data of the participants in the Nagoya Longitudinal Study for Frail Elderly (NLS-FE) and data on the mortality and hospitalization of these participants during the 3-year follow-up period.

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Details of participants (N = 1,875, aged 65–104) and the NLS-FE have been published elsewhere.[8,9] The participants were eligible for a long-term care insurance (LTCI) program, lived in Nagoya City, and were provided various kinds of community-based services from the Nagoya City Health Care Service Foundation for Older People, which has 17 visiting nursing stations associated with care-managing centers. These NLS-FE participants, who were enrolled between December 1, 2003, and January 31, 2004, were scheduled to undergo comprehensive in-home assessments by trained nurses at baseline and at 6, 12, and 24 months. Data were collected about any important events in the lives of the participants, including admission to the hospital and mortality at 3-month intervals during the 3-year follow-up. Written informed consent for participation, according to procedures approved by the institutional review board of Nagoya University Graduate School of Medicine, was obtained from the patients or, for those with substantial cognitive impairment, from a surrogate (usually the closest relative or legal guardian). Because the 103 participants who were taking no prescribed medications at baseline were excluded, the study population consisted of 1,772 community-dwelling disabled elderly people (611 men and 1,161 women, aged ≥65).

Data Collection

The data were collected at the clients' homes from standardized interviews with patients or surrogates and caregivers and from care-managing center records taken by trained nurses. The trained nurses administered a standardized interview developed by the investigators that included participant's demographic characteristics; general socioeconomic status; living arrangement; use of formal care or medical service; overall health and nutritional status; presence of hearing, visual, or eating disorder; and medication matters as described below. When the participants were unable to answer or had cognitive impairment, surrogates and caregivers were asked. The data included a rating for 10 ADLs (feeding, bed mobility, bathing, grooming, dressing, using the toilet, walking inside and outside, transferring, and using stairs) using a summary score ranging from 0 (total disability) to 20 (no disability) and a rating for eight IADLs (using the telephone, grocery shopping, preparing meals, doing housework, doing laundry, taking medications, managing money, and using transportation systems) using a summary score ranging from 0 (total disability) to 8 (no disability). Information on the following physician-diagnosed chronic conditions was obtained from care-managing center records: ischemic heart disease, congestive heart failure, cerebrovascular disease, diabetes mellitus, dementia, cancer, hypertension, and other diseases from the Charlson Comorbidity Index,[10] which represents the sum of weighted indexes, taking into account the number and seriousness of preexisting comorbid conditions.

Self-reported difficulty with self-medication management was assessed by asking participants whether they had any difficulty managing medication, as follows: "Do you have any difficulty removing prescribed medicines from the medication container or taking medications? Do you need reminding to take medications?" When participants said that they had any difficulty or need reminding, they were categorized as having difficulty with self-medication management. When the participants were unable to answer or had cognitive impairment, surrogates and caregivers were asked. The data also included the number of prescribed medications. Information about regular prescribed medications was recorded based on prescription records. Clients eligible for LTCI had their own primary care physicians submit a report on their clinical status every 6 months. The participants or family were also asked whether they were receiving any assistance in taking medication or medication management by others, including reminding to take medications, opening the container, pouring the medication, handing the medication to the patient, guiding the patient's hand to bring the medication to his or her mouth, and supervision.

The adherence rate to the prescribed medication was defined as the total number of pills taken divided by the total number of prescribed pills that should have been taken and assessed according to the self-reported average medication adherence during 1 month, as recorded at the baseline interview. Adherence was averaged across the different classes of medications. When the participants were not able to respond, adherence was assessed by asking the help of a caregiver. The adherence rate was divided into two categories: 80% to 100% and less than 80%.

Statistical Analysis

An analysis of variance with a Bonferroni correction and the chi-square test were used to compare differences between participants who did not need assistance taking medication, those receiving medication management support, and those not receiving medication management support.

Cox proportional hazard models and the Kaplan-Meier method were used to assess the association between need for medication support or the presence or absence of medication support at baseline and mortality or hospitalization during a 3-year period. To create an ideal model for a multivariate Cox proportional hazards model, the association between each covariate and 3-year mortality or hospitalization during the 3-year period was evaluated using the univariate Cox proportional hazards model. The covariates included in the multivariate analysis were variables associated with mortality or hospitalization at $P < .05$ in univariate analysis. The risk of a variable was expressed as a hazard ratio (HR) with a corresponding 95% confidence interval (CI). All analyses were performed using SPSS, version 15.0 (SPSS Inc., Chicago, IL). A probability value of $< .05$ was considered significant.

RESULTS

Of 1,772 participants, 681 did not have difficulty with self-medication management, and 1,091 did. Of the 1,091 who had difficulty with self-medication, 929 had assistance, and 162 did not. At baseline, participants who had assistance with medication were older and lower baseline levels of ADL and IADL functions, a higher Charlson comorbidity index, and higher prevalence of congestive heart failure, cerebrovascular disease, and dementia than those who did not have difficulty and those who had difficulty but did not have assistance (Table 1). Participants who did not have

Table 1. Baseline Characteristics and Adverse Outcomes of Participants with and without Difficulty with Self-Medication Management

Characteristics and Outcomes	No Difficulty n = 681	Difficulty n = 1,091		P-Value
		Having Assistance n = 929	No Assistance n = 162	
Baseline characteristics				
Men/women, n (% of men)	191/490 (28.0)	368/561 (39.6)	52/110 (32.1)	<.001
Age, mean ± SD[*,†]	78.9 ± 6.8	81.4 ± 8.0	79.9 ± 7.6	<.001
Activities of daily living, mean ± SD (range 0–20)[*,‡]	17.4 ± 3.0	9.2 ± 6.5	14.5 ± 4.6	<.001
Instrumental activities of daily living, mean ± SD (range 0–8)[*,§]	5.7 ± 1.5	1.4 ± 1.8	3.4 ± 1.7	<.001
Charlson Comorbidity Index, mean ± SD[*,‖]	1.4 ± 1.4	2.5 ± 1.6	1.7 ± 1.3	<.001
Chronic diseases (% of total)				
Ischemic heart disease	12.7	13.5	7.2	.09
Congestive heart failure	6.4	10.5	9.8	.02
Cerebrovascular disease	20.0	48.4	28.8	<.001
Diabetes mellitus	12.2	13.4	9.8	.44
Dementia	5.7	58.4	16.0	<.001
Cancer	10.6	8.7	7.8	.35
Hypertension	26.3	25.8	16.7	.03
Number of medications (% of total)				
1–2	15.0	20.8	13.0	
3–5	45.1	44.2	39.5	.002
≥6	39.8	35.0	47.5	
Adherence (% of total)				
80–100%	90.7	86.9	76.5	<.001
<80%	9.3	13.1	23.5	
Regular medical examination (% of total)	53.3	64.9	58.0	<.001
Living alone (% of total)	41.7	9.0	19.9	<.001
Having caregiver (% of total)	68.7	96.4	85.2	<.001
Adverse outcomes (% of total)				
Hospitalization during study period	36.3	46.8	46.9	<.001
Mortality	14.0	32.2	18.5	<.001

* Analysis of variance; others were analyzed using the chi-square test.
† No difficulty versus having assistance, $P<.001$; no difficulty versus no assistance, $P=.34$; having assistance versus no assistance: $P=.05$.
‡ No difficulty versus having assistance, $P<.001$; no difficulty versus no assistance, $P<.001$; having assistance versus no assistance, $P<.001$.
§ No difficulty versus having assistance, $P<.001$; no difficulty versus no assistance, $P<.001$; having assistance versus no assistance, $P<.001$.
‖ No difficulty versus having assistance, $P<.001$; no difficulty versus no assistance, $P=.16$; having assistance versus no assistance, $P<.001$.
SD = standard deviation.

assistance with medication had higher rates of poor medication adherence (<80%). Participants who had assistance with medication had a higher rate of mortality during the 3-year follow-up.

During the 3-year follow-up, 424 participants died, and 758 were admitted to hospitals. Table 2 provides the results of the crude and multivariate Cox proportional hazards models to examine the HRs for mortality and hospitalization for participants who reported difficulty with self-medication management or unmet need for medication assistance during the 3-year study period. In the crude models, difficulty with self-medication management was significantly associated with mortality (HR = 2.48, 95% CI = 1.97–3.11) and hospitalization (HR = 1.51, 95% CI = 1.30–1.76), although these associations were attenuated after adjusting for potential confounders (mortality, HR = 0.98, 95% CI = 0.72–1.32; hospitalization, HR = 1.13, 95% CI = 0.93–1.38). In those who reported difficulty with self-medication management, receipt of

medication assistance was significantly associated with a higher risk for 3-year mortality (HR = 2.70, 95% CI = 2.14–3.40) and hospitalization (HR = 1.53, 95% CI = 1.31–1.79) in the crude model, whereas not receiving medication assistance was associated with hospitalization (HR = 1.41, 95% CI = 1.09–1.83) but not with mortality (HR = 1.37, 95% CI = 0.91–2.06). The adjustment for confounders abolished the association between presence of medication assistance and risk of mortality (HR = 1.00, 95% CI = 0.72–1.38) and hospitalization (HR = 1.06, 95% CI = 0.86–1.32), although the association between lack of support and hospitalization during study period persisted after the adjustment (HR = 1.32, 95% CI = 1.01–1.73). The inclusion of adherence to medication (80–100% and <80%) in the multivariate analysis led to a nonsignificant risk of unmet medication support need for hospitalization during the study period, but the HR remained rather constant (HR = 1.31, 95% CI = 0.99–1.72). Figure 1 shows the multivariate-adjusted Kaplan-Meier plots of

Table 2. Cox Proportional Hazard Models for Mortality or Hospitalization During a 3-Year Period

| | | Difficulty with Self-Medication | |
| | Difficulty with Self-Medication | Receiving Assistance | Absence of Assistance |
Mortality and Hospitalization	Hazard Ratio (95% Confidence Interval)		
Mortality			
Crude model	2.48 (1.97–3.11)	2.70 (2.14–3.40)	1.37 (0.91–2.06)
Adjusted*	0.98 (0.72–1.32)	1.00 (0.72–1.38)	0.92 (0.60–1.42)
Hospitalization			
Crude model	1.51 (1.30–1.76)	1.53 (1.31–1.79)	1.41 (1.09–1.83)
Adjusted†	1.13 (0.93–1.38)	1.06 (0.86–1.32)	1.32 (1.01–1.73)

* Adjusted for sex, age, activity of daily living (ADL) score, living arrangement, regular medical examination, number of regular medications, and presence or absence of chronic diseases, including congestive heart failure, dementia, cancer, and hypertension.
† Adjusted for sex, age, ADL score, living arrangement, regular medical examination, number of regular medications, and presence or absence of chronic diseases, including congestive heart failure, cerebrovascular disease, diabetes mellitus, and cancer.

survival and hospitalization during the 3-year follow-up in participants according to the presence or absence of difficulty with self-medication management, or receiving medication assistance.

DISCUSSION

The present study found that difficulty with self-medication management in elderly people, in other words in elderly people who require medication assistance, was associated with higher all-cause mortality and all-cause hospitalization during a 3-year follow-up period, although these associations disappeared after adjusting for potential confounders. However, in participants who had difficulty with self-medication management, the crude model demonstrated that receipt of medication assistance was associated with higher mortality and hospitalization during the study period. Needing but not receiving assistance was as-
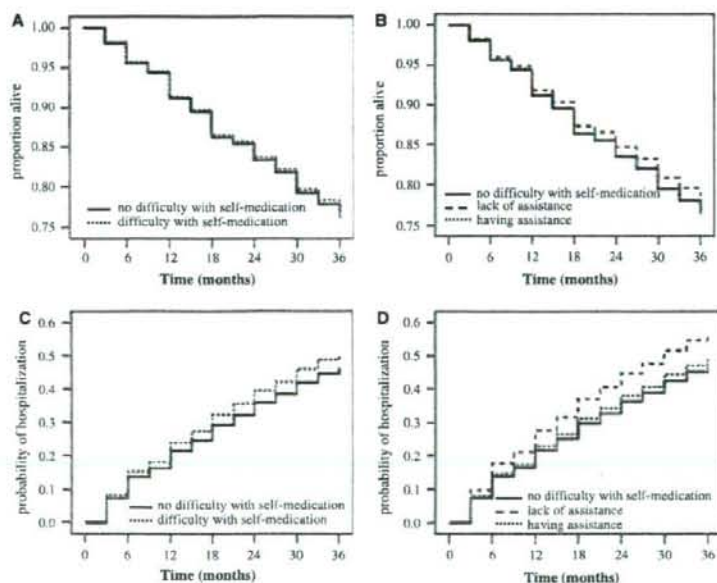

Figure 1. Multivariate adjusted Kaplan-Meier plots of survival (A, B) and hospitalization (C, D) during the 3-year follow-up in participants according to the presence or absence of difficulty with self-medication management, or receiving medication assistance. Gender, age, activities of daily living (ADL) score, living arrangement, regular medical checkup, number of regular medications, and presence or absence of chronic diseases including congestive heart failure, dementia, cancer, and hypertension were included as covariates for mortality analysis and gender and age, ADL score, living arrangement, regular medical checkup, number of regular medications, and presence or absence of chronic diseases including congestive heart failure, cerebrovascular disease, diabetes mellitus, and cancer were included as covariates for hospitalization analysis. (B) The lines of "having assistance" overlap the lines of no difficulty with self-medication.

sociated with more hospitalization but not greater mortality than having no difficulty, although after adjustment for potential confounders, the association between 3-year mortality and hospitalization and receipt of medication management assistance disappeared, suggesting that higher risk of mortality or hospitalization in participants receiving assistance was related to their baseline characteristics, including age, ADL status, comorbidity, and living arrangement. In contrast, the association between hospitalization during the 3-year study period and the absence of medication management assistance in those having difficulty with self-management persisted even after full adjustment for potential confounders.

These observations may indicate that unmet need for assistance with medication management is a risk factor of all-cause hospitalization in community-dwelling older people with disabilities. The lack of help to appropriately self-manage complicated medication regimens seems to lead to poor adherence to medication regimens.[11] Poorer adherence was observed in participants who had no help for medication than in those who reported no difficulty with medication management or in participants receiving medication assistance. Poor adherence to medication regimens accounts for substantial worsening of disease and health condition.[12-14] In addition, it has been reported that a high percentage of medication-related hospital admissions are due to poor medication adherence.[13,15] These results suggest that the poor adherence contributes to the higher risk of hospitalization at least in part because of unmet need for support for medication management in community-dwelling disabled older people. However, in the present study, the inclusion of medication regimen did not greatly influence the HR of the lack of needed assistance for all-cause hospitalization adherence in the multivariate analysis, which suggests that poor adherence may not be a major cause of the higher hospitalization in participants who do not receive help for medication management. It has been demonstrated that the adverse drug events in older people are a major cause of hospitalization in older people.[16,17] The lack of needed assistance may lead not only to poor adherence to medication regimens, but also to the adverse drug events that the inappropriate use of drugs causes, including taking the wrong dose and inappropriate frequency or route of administration.

Reasons other than taking medication might be involved in the greater risk of hospital admission in those with an unmet need for medication management. The unmet needs for medication support by family or formal community-based services under the LTCI program may also reflect the multiple types of unmet needs for various kinds of ADL tasks. Poorer total informal care levels, as assessed by visiting nurses or care managers, were observed in participants who did not receive the help that they needed with medication management than in those who had medication support (data not shown). These total unmet needs for care may contribute to substantial worsening of disease and increase the risk of hospitalization in community-dwelling older people with disabilities.

This study had important limitations. Because of the observational design, the marginal significance of the unmet need for medication support for hospitalization risk could be due to unmeasured factors, including the severity of chronic diseases of patients, health conditions of caregivers, socioeconomic status, educational attainment, and quantity and quality of community services. In the analysis, baseline data about medication management and medication use were included, but changes in care and medication during the follow-up period were not considered. In addition, these findings may not be generalizable to other populations, given that health practices, a variety of social and economic factors, ethnic attitudes about caring for very old people, and cost may have influenced them. The self-reported ability to manage medication and the self-reported average medication adherence may not have been accurate or reflected precise ability and adherence rate. More-objective and -precise assessments of difficulty with medication management and adherence rate should be used in the future research in this area, and further studies are needed to determine what kind of medication management problems are involved in the poor outcomes of disabled elderly people and what kind of medication supports are important to improve the outcomes.

The present study demonstrated that lack of medication assistance in those needing medication support was associated with higher risk of hospitalization. Healthcare providers and families should recognize the importance of evaluating the ability of older people to independently administer medications and provide the appropriate medication support for subjects who need medication assistance.

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J-SHAPED RELATIONSHIP BETWEEN RESTING PULSE RATE AND ALL-CAUSE MORTALITY IN COMMUNITY-DWELLING OLDER PEOPLE WITH DISABILITIES

To the Editor: It has been demonstrated that a high resting heart (pulse) rate (PR), particularly in adult men, is associated with greater risk for cardiovascular and all-cause mortality.[1,2] Although there have been only limited studies that have examined the relationship between PR and mortality in older people, conflicting results have been published. In older women, there is reported to be a linear relationship between heart rate and mortality,[3] although others have been unable to confirm this association.[4] In addition, the association between mortality and resting PR in disabled older people remains unknown. In the present study, we examined the influence of PR on the all-cause mortality of community-dwelling older people with disabilities.

   The study analyzed the baseline data of a subgroup of participants in the Nagoya Longitudinal Study of the Frail Elderly (NLS-FE)[5,6] and mortality during a 3-year follow-up period. The study population consisted of 932 community-dwelling older people (347 men, 585 women; mean age ± standard deviation 80.4 ± 7.9) who were provided with various home care services under a long-term care insurance program. The baseline data included the subjects' demographic characteristics and a rating for basic activities of daily living (ADLs). Additional information obtained from records of care-managing centers included the following physician-diagnosed chronic conditions: ischemic heart disease, congestive heart failure, cerebrovascular dis-

ease, diabetes mellitus, dementia, neoplasia, hypertension, and pressure ulcers. Trained visiting nurses at home determined resting PR per minute and blood pressure, and PR was categorized into quartiles (Quartile 1: ≤67 beats per minute (bpm), mean 61.5 ± 4.8, n = 231; Quartile 2: 68–72 bpm, 70.8 ± 1.6, n = 265; Quartile 3: 73–80 bpm, 77.6 ± 1.9, n = 236; Quartile 4: ≥81 bpm, 88.1 ± 6.2, n = 200). Data concerning any important events in the lives of the participants, including mortality, were collected at 3-month intervals. Cox proportional hazard models were used to assess the association between resting PR at baseline and 3-year all-cause mortality.

   There were no statistical differences in the proportion of men, average age, ADL mean score, or blood pressure between participants divided into quartiles of resting PR at baseline. In the unadjusted Cox hazard model, Quartiles 1, 3, and 4 were significantly associated with risk for 3-year mortality (hazard ratio (HR) = 1.49, 95% confidence interval (CI) = 1.07–2.09; HR = 1.59, 95%CI = 1.14–2.21; and HR = 2.22, 95%CI = 1.60–3.09, respectively, in comparison with Quartile 2). Figure 1A shows the Kaplan–Meier survival curves for each quartile. After adjusting for sex, age, ADL score, systolic and diastolic blood pressure, and the presence of chronic disease as described above, Quartiles 1, 3, and 4 also predicted greater risk for 3-year all-cause mortality (HR = 1.56, 95%CI = 1.07–2.28; HR = 1.58, 95%CI = 1.08–2.32; HR = 2.53, 95%CI = 1.53–3.21, respectively, in comparison with Quartile 2), suggesting J-shaped relationships between resting PR and 3-year all-cause mortality (Figure 1B).

   In the present study, we demonstrated for the first time the J-shaped relationships between Quartile 2, with the lowest mortality, and Quartiles 1, 3, and 4 with respect to resting PR and 3-year all-cause mortality of community-dwelling older with disabilities. Previous studies have found a linear relationship between resting heart rate and mortality in adults and older people.[1–3] The explanation for this J-shaped association in disabled older people remain unclear. A statistically significantly higher prevalence of ischemic heart disease in Quartile 1 was observed in the present cohort than in Quartile 2 (data not shown), al-
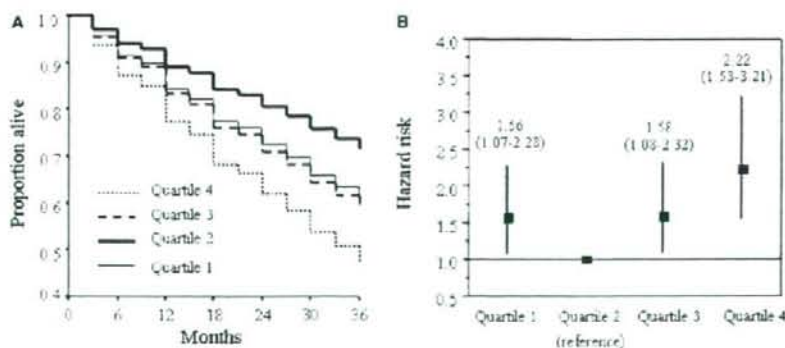
Figure 1. (A) Kaplan–Meier survival curves over the 3-year study period according to quartiles of baseline pulse rate (≤ 67, 68–71, 72–80, ≥ 81). Log rank test: *P* < .001. (B) Risk of death according to quartiles of pulse rate, adjusting for sex, age, activity of daily living score, presence of chronic diseases, and systolic and diastolic blood pressure. Black squares are point estimates from a Cox proportional hazard model adjusting for potential confounders. Error bars represent 95% confidence intervals.

though no differences were detected in the prevalence of the other examined chronic diseases between quartiles. However, even after adjusting for comorbidity including ischemic heart disease, significantly higher mortality continued to be observed in Quartile 1 than in Quartile 2. It is possible that Quartile 1 of the present cohort had health problems relevant to mortality that were not included in the analysis. Thus, the present results should be interpreted with caution and taking the following limitations into account; the measurement of PR instead of heart rate using electrocardiograms reduces the precision of the estimation, and a certain number of possible confounding factors that may affect PR, such as the use of prescribed medications (e.g., beta-blockers), were not tested in our cohort.

Feeling the pulse has a long tradition in medicine as a noninvasive, easily obtained indicator of illness. Resting PR seems to be an important predictor of survival and can be used to select patients at higher risk in community-dwelling elderly people with disabilities.

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INFORMED CONSENT IN OLDER PATIENTS WITH ACUTE CORONARY SYNDROMES OFFERED INVASIVE MANAGEMENT

To the Editor: Persons aged 75 and older constitute 6% of the U.S. population but account for 42% of hospital admissions for acute myocardial infarction (AMI),[1] and this proportion will likely increase in the decades ahead. Urgent percutaneous coronary intervention (PCI) has become standard practice for managing AMI in many centers, and it may be the preferred therapy for older patients with AMI.[2,3] As with any medical procedure, the principles of autonomy and beneficence require that informed consent be provided to the patient or surrogate before cardiac catheterization. Truly informed consent requires not only disclosure, but also a fundamental understanding of the disclosed information. Obtaining informed consent should be viewed as part of the patient education process before catheterization so that patients become well-informed, responsible, and willing members of the team.[4]

Elderly patients with AMI requiring urgent PCI have many barriers to truly informed consent, including poor eyesight and hearing, cognitive impairment, and difficulty understanding medical terminology. As the pressure to perform PCI promptly to improve clinical outcomes continues to increase, the ability of the physician to focus on obtaining truly informed consent becomes even more difficult. Although the aging population presents unique challenges to providing medical care, it is not known whether the current system of obtaining informed consent for PCI is adequate. This study sought to assess how well elderly patients are informed about cardiac catheterization in an urgent setting and to identify mitigating factors that might have influenced the success of the process.

Seventeen patients aged 75 and older and 18 patients younger than 75 who presented with acute coronary syndromes requiring urgent PCI were interviewed after catheterization (within 48 hours). As shown in Table 1, the two groups were similar, except that older patients had lower Mini-Mental State Examination (MMSE) scores,[5] lower estimated glomerular filtration rates,[6] and lower hemoglobin levels.

A standard 15-item questionnaire was used to assess recall about potential benefits and risks associated with PCI and to evaluate the participant's experience with the consent process. Successful informed consent was defined as the ability to recall at least one benefit and at least one risk other than death.

Eight of 17 older patients (47%) achieved successful informed consent, compared with 17 of 18 younger patients (94%; $P = .003$). There were no significant differences between the groups' reported experiences with the consent process. All patients reported having received sufficient in-

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Original Research

Effects of Acupuncture/Moxibustion and/or Massage Program on Levels of Health-related Quality of Life and Symptom Distress in Frail Elderly

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Abstract

[AIM] Recently, the demand for acupuncture/moxibustion and massage as adjunct therapies to medical treatment has been on the rise. A number of papers have highlighted the positive effect of these therapies. However, to our knowledge, few studies have reported on the effect of acupuncture/moxibustion and massage on the frail elderly. Therefore, we conducted a pilot study to evaluate the effect of acupuncture/moxibustion and/-or massage on the quality of life (QOL) and the level of severity of 20 symptoms prevalent among the frail elderly.

[DESIGN] Observational study

[SETTINGS] Twenty-four clinics belonging to the Society of Practitioners of Acupuncture, Moxibution and Massage, the Acupuncture and Moxibustion Association, and the Association of Licensed Massage Professionals.

[PATIENTS] Elderly users 65 years and above, willing to respond to study questions, able to stand up, attending hospital as outpatient, and not having received acupuncture/moxibustion or massage within 3 months of enrollment.

[INTERVENTION] Thirty-minute sessions of customized therapy consisting of acupuncture/moxibution and/or Japanese-style massage, administered at differing frequencies depending on the patient's needs.

[MAIN OUTCOME MEASURE] Health-related QOL (Short Form-36) and symptom severity were evaluated at baseline and at 3 months.

[RESULTS] For the 8 SF-36 sub-scales, namely Role Physical, Role Emotional, Physical Functioning, Social Functioning, Mental Health, Vitality, Body Pain, and General Health, the figures indicate clinically significant change over time for these patients. In anorexia, nausea, loss of sleep, depression, anxiety, shoulder or neck stiffness, back pain, lower back pain, and arthralgia, there were significant improvements over time ($p=0.04$, 0.05, <0.01, 0.01, 0.01, 0.01, 0.02, <0.01 and 0.03, respectively).

[CONCLUSIONS] Our study suggested that acupuncture/moxibustion and/or massage have a positive effect on physical and mental health among the frail elderly. Larger studies are nevertheless needed to confirm these results.

Key words: Acupuncture/Moxibustion, Massage, Health-related Quality of Life, Symptom Distress, Elderly

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I . Introduction

One of the byproducts of the aging of the population is a rise in the number of frail elderly patients attending hospitals as outpatient. The aged are vulnerable to various chronic medical problems that are difficult to alleviate by relying solely on Western medicine; attention has thus recently increasingly focused on ways to enhance the quality of life of the elderly through alternative methods. The steadily increasing elderly population intensifies the need for integrating complementary and alternative treatment with Western medicine[1].

In Japan, acupuncture/moxibustion and massage have been used since ancient times; these therapies are offered by trained professionals and are partially covered by public medical insurance as an alternative medical service[1]. Recently, the demand for acupuncture/moxibustion and massage as adjunct therapies to medical treatment has been on the rise[1]. There is now a need for "evidence-based alternative medicine" in addition to evidence-based medicine[1,2]. As for acupuncture/moxibustion and massage, a number of papers have highlighted their positive effect[3-9]. However, to our knowledge, few studies have reported on the effect of acupuncture/moxibustion and massage on the frail elderly.

We therefore conducted a pilot observational study to evaluate the effect of acupuncture/moxibustion and/or massage on the quality of life (QOL) and the level of severity of twenty symptoms prevalent among the frail elderly.

II . Materials and Methods

1) Study population (Figure 1)

We contacted the following associations in Aichi prefecture to explain our study procedure: the Society of Practitioners of Acupuncture, Moxibution and Massage, the Acupuncture and Moxibustion Association, and the Association of Licensed Massage Professionals. These three societies are non-profit organizations comprised of licensed practitioners of acupuncture/moxibution and/or massage. Twenty-four practitioners agreed to join our study. Patients were recruited for a period of eight months, from December 2004 through July 2005. The study practitioners were in charge of recruitment. The inclusion criteria were as follows: 65 years and above, able to respond to study questions, able to stand up, attending hospital as outpatient, and not having received acupuncture/moxibustion or massage within 3 months of enrollment. All eligible participants were required to sign informed consent forms. Also, this study was designed to allow patients to respond anonymously to questions. Because there is no definite agreement on the meaning of the term "frail" in the world[10], we defined the "frail elderly" as elderly who can stand up but who attend a hospital as outpatient, as mentioned in our study inclusion criteria.

2) Treatment

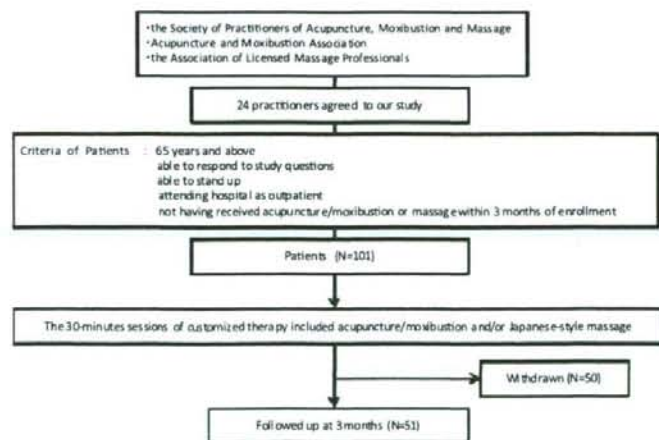At each clinic, patients received 30-minute sessions of customized therapy consisting of acupunc-

Figure 1. Flow chart for study population.

ture/moxibution and/or Japanese-style massage. Some applicants also received hot pack therapy, photothermal therapy, kinesitherapy, and other alternative treatments. Japanese-style massage is a two-faceted medical therapy comprised of: therapeutic massage and nursing massage[1]. Both approaches consist predominantly of rubbing and finger-pressure techniques. Therapeutic massage aims at the direct treatment of illnesses in internal medicine, orthopedics, neurology and other fields. Meanwhile, nursing massage aims at the indirect treatment of illnesses, acting to prevent or improve the patient's weakness or fatigue. Kinesitherapy includes sitting balance exercises, sitting up exercises, standing-up exercises, gait exercises, and range of motion (ROM) exercises.

In Japan, acupuncture/moxibustion and massage are widely used as joint therapy[1]. Therefore, we opted to consider them as a single therapy unit rather than as distinct therapies based on the advice of the above-mentioned associations. We therefore analyzed and assessed the effectiveness of these therapies as a whole.

3) Baseline and Follow-up Assessment

Using a standard questionnaire, assessments were performed at baseline and at 3 months. To avoid the influence of any interaction with the practitioner on the patient's replies, both assessments were conducted prior to the visit of the practitioner. The questionnaire broached two main issues: health-related QOL and symptom severity. The health-related QOL of participants was assessed based on The Medical Outcomes Study Short Form 36-Item Health Survey (SF-36), which is a widely used, standardized questionnaire consisting of 36 questions[11,12]. We calculated the usual eight-dimension scores. Symptom severity was assessed based on our original questionnaire which focused on the following twenty symptoms: anorexia, nausea, constipation, shortness of breath/palpitation, cough/sputum, weakness, indigestion, dizziness, loss of sleep, exhaustion, chilling/rush, ringing, irritation, depression, anxiety, stiffness in shoulders and neck, back pain, lower back pain, arthralgia, and numbness. Symptom severity was assessed on a 5-item scale (4=always, 3=often, 2=occasionally, 1=seldom, 0=never) based on answers to the following symptom experience: "To what extent do you experience the following symptom in daily life?" For the follow-up assessment, we used a questionnaire or the telephone to inquire about the content and frequency of the therapies that the patients had received.

4) Statistical analysis

Values are reported as mean ± standard deviation. We analyzed the significance of differences in

Table 1. Baseline characteristics of subjects (N=51)

Variables		Mean/ Number	SD/ %
Age (y)		74.67	6.07
Gender (female)		36	70.59
Disease			
	gout	0	0.00
	rheumatism	2	3.92
	arthritis	10	19.61
	hernia	4	7.84
	hypertension	20	39.22
	diabetes	7	13.73
	hyperlipidemia	7	13.73
	cerebrovascular disease	2	3.92
	cardiovascular disease	5	9.80
	cancer	1	1.96
	pulmonary disease	2	3.92
	gastrointestinal disease	4	7.84
	hepatobiliary and spleen disease	0	0.00
	genitourinary disease	5	9.80
	gynaecological disease	1	1.96
	allergy	1	1.96
	others	9	17.65

Table 2. Frequency of therapy administration (N=51)

Item	1/month	2-3/montl	1/week	2/week	3/week	4/week
			Number			
Acupuncture/Moxibustion	0	4	14	15	7	1
Massage	0	3	6	11	1	0
Hot pack	0	1	7	6	4	0
Other therapies*	1	0	2	1	1	1

* Including photothermal therapy or kinesitherapy.

Table 3. Change in SF-36 scores.

Sub-scales	SF-36 scores (Mean±SD)		
	Baseline	3 months	P
Role physical (RF)	45.85±32.23	69.60±26.40	0.000
Role emotional (RE)	51.48±36.56	76.48±28.39	0.000
Physical functioning (PF)	52.87±32.16	65.05±27.41	0.001
Social functioning (SF)	50.82±30.78	72.83±27.17	0.000
Mental health (MH)	55.44±22.93	67.04±22.70	0.002
Vitality (VT)	46.00±22.82	55.45±20.74	0.021
Bodily pain (BP)	37.35±22.82	53.20±21.16	0.002
General health (GH)	43.22±19.37	53.24±21.35	0.003

Table 4. Change in symptom levels.

Symptom	Distress scores (Mean±SD)		
	Baseline	3 months	P
anorexia	1.86 ± 1.36	1.44 ± 0.68	0.040
nausea	1.44 ± 0.98	1.10 ± 0.37	0.048
constipation	2.61 ± 1.59	2.24 ± 1.10	0.159
short of breath/palpitation	1.89 ± 1.10	1.86 ± 1.12	0.454
cough/sputum	1.65 ± 0.88	1.59 ± 1.00	0.851
weakness	1.98 ± 1.16	1.88 ± 1.03	0.765
indigestion	1.83 ± 1.13	1.78 ± 0.99	0.345
dizziness	1.79 ± 0.97	1.73 ± 1.04	0.686
loss of sleep	2.49 ± 1.38	2.02 ± 1.01	0.003
exhaustion	3.00 ± 1.28	2.74 ± 1.31	0.828
chilling/rush	2.28 ± 1.73	2.10 ± 1.19	0.098
ringing	1.53 ± 1.06	1.61 ± 1.03	0.561
irritation	2.35 ± 1.48	2.12 ± 1.33	0.247
depression	2.28 ± 1.53	1.75 ± 0.93	0.009
anxiety	2.53 ± 1.33	2.09 ± 1.04	0.011
shoulder/neck stiffness	3.33 ± 1.39	2.80 ± 1.30	0.014
back pain	2.68 ± 1.55	2.03 ± 1.22	0.017
lower back pain	3.43 ± 1.37	2.74 ± 0.99	0.001
arthralgia	3.14 ± 1.64	2.59 ± 1.28	0.030
numbness	2.34 ± 1.36	1.91 ± 1.00	0.177

measurements before and after the program, using the Wilcoxon signed-ranks test. P values < 0.05 were considered significant. Statistical analyses were performed with Statview J-5.0.

III. Results

A total of 101 patients were recruited for the present study. Fifty-one patients completed the 3-month therapy and pre- and post-evaluations. The remaining 50 patients withdrew for personal reasons and could not be followed-up. The baseline characteristics of the 51 study participants followed-up at 3 months are shown in Table 1. A greater number of subjects were female. Hypertension was the most frequent complication, followed by arthritis. The frequency of therapy the subjects received is shown in Table 2. Forty of the 51 subjects received acupuncture/moxibustion, and twenty-one received massage therapy. As for additional treatment, 19 subjects received hot-pack therapy. Twice a week was the most common treatment frequency for acupuncture, moxibustion and massage.

The effect of acupuncture/moxibustion and/or massage on the SF-36 is shown in Table 3. In the score of 8 SF-36 sub-scales, namely Role Physical, Role Emotional, Physical Functioning, Social Functioning, Mental Health, Vitality, Body Pain, and General Health, the figures indicate clinically significant change over time for the 51 study participants.

The effect of acupuncture/moxibustion and/or massage on levels of symptoms is shown in Table 4. In anorexia, nausea, loss of sleep, depression, anxiety, shoulder or neck stiffness, back pain, lower back pain, and arthralgia, there were significant improvements over time (p=0.04, 0.05, <0.01, 0.01, 0.01, 0.01, 0.02, <0.01 and 0.03, respectively).

IV. Discussion

This pilot study examined the influence of acupuncture/moxibustion and/or massage therapy programs on the QOL of frail elderly patients with chronic diseases. These therapies are considered to be important features of complementary alternative medicine (CAM.) Despite the increasing popularity of CAM therapy use by patients with chronic diseases or pre-symptomatic disease (Mibyo), very few studies concerning the benefits of CAM therapy a have so far been conducted, especially in Japan. We believe that the present study, despite certain limitations such as its restricted size, is valuable in planning additional trials to assess the benefits of

CAM therapy for elderly patients.

We experienced difficulties in recruiting frail elderly patients willing to take part in this pilot study. The condition of some of the patients may have been severe due to cancer and cardiovascular disease. Eligibility should have been restricted to patients with minor illnesses. Also, nearly half of the recruited patients who were not satisfied with the therapy or who recovered completely were inclined not to seek further treatment. It is possible that the initial eligibility criteria for this prospective study were not adequate.

Study participants reported decreased levels of distress symptoms such as anorexia, nausea, loss of sleep, depression, anxiety, shoulder or neck stiffness, back pain, lower back pain, and arthralgia, as shown by the 20-item subjective distress scores at the 3-month follow-up. Various studies have documented the physical and/or mental benefits of acupuncture/moxibustion[7,8] or massage[3-6,13]. The present study corroborated the value of these therapies and revealed a range of benefits for frail elderly patients. A number of studies have reported that endogenous opioid peptides are important substrates for mediation of acupuncture analgesia[9]. Others have revealed that massage decreases the stress response and promotes relaxation. Because distress symptoms have a negative effect on the QOL of the frail elderly, our results offer valuable tools toward the improvement of the QOL of frail elderly, which is one of the aims of geriatric medicine.

Also, our study suggested that acupuncture/moxibustion and/or massage have a positive effect on physical and mental health, as shown by the SF-36 results. Although it is difficult to make an accurate evaluation on QOL[1], SF-36 is one of the most widely used and reliable scales of QOL[7]. We can therefore assume that our results are consistent enough to confirm the value of the therapy in improving the QOL of the frail elderly.

However, our results should nevertheless be interpreted with caution due to certain limitations with our study. First, because participants might receive other treatments in the hospital during the study period, we should have investigated the medical treatments the patients had received from other sources in order to accurately examine the effects of acupuncture/moxibustion and/or massage programs. Second, the administration procedures of acupuncture/moxibustion therapy differed from practitioner to practitioner. We did not precisely investigate the methods used to administer acupuncture/

moxibustion such as needling procedure, length and size of the needles, acupuncture points, depth of needle insertion, and number of moxa cones. Also, because intervention frequency is often tailored to the individual needs of patients, we were unable to properly assess the dose-dependent effect of acupuncture/moxibustion or massage therapy. Third, the scale of this pilot study was too limited to allow us to confirm the effect of acupuncture/ moxibustion and/or massage according to disease or symptom. Finally, our results were biased because the practitioners knew the aim of the study and also because a number of patients dissatisfied with therapy ceased it. A full RCT trial is required to examine whether the changes over time are the result of the program or are the result of the placebo effect.

V. Conclusion

Our study suggested that acupuncture, moxibustion and massage have a positive effect on the physical and mental health of the frail elderly.

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Caregiver burden among Japanese informal caregivers of cognitively impaired elderly in community settings

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Abstract

Because dementia is a progressive disease, formal long-term care providers and care managers need information on how the severity of cognitive impairment affects caregiver burden in order to better assist family caregivers. However, research to guide care providers in behavioral symptom-management is not well developed. The purpose of this study was to examine the relationship between dementia status and burden of family caregivers. The subjects were 1875 community-dwelling elderly eligible for public long-term care insurance. The data we used in this analysis included the caregivers' and dependents' characteristics. The main outcome was subjective caregiver burden assessed by the Japanese version of the Zarit Burden Interview (J-ZBI). A total of 1559 pairs of dependents and caregivers were included in the analysis. The pairs were sorted into three mutually exclusive categories: no dementia, mild dementia, and severe dementia. Two hundred sixty-one dependents had severe dementia, and 725 had mild dementia. Although differences were found among the dementia categories in levels of caregiver burden according to the J-ZBI before and after adjusting for these baseline variables, the odds ratios equal nearly 1. The present study shows that severity of dementia is not associated with caregiver burden in Japan.
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Keywords: Caregiver burden; Dementia in elderly; Behavioral disorder

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1. Introduction

Although the trend toward home care for elderly people is part of a social movement designed to improve long-term care in Japan (Kawamoto et al., 1999; Hirakawa et al., 2006b), family caregivers for the demented elderly still have two major concerns: caregiver burden and their ability to provide care (Kameda et al., 2001). Because dementia is a progressive disease, formal long-term care providers and care managers need information on how the severity of cognitive impairment affects caregiver burden in order to better assist family caregivers. While it is established that the behavioral and psychological symptoms of dementia are important sources of caregiver burden in Western countries (Coen et al., 1997; Donaldson et al., 1998; Asada et al., 1999; Hart et al., 2003), research to guide long-term care providers in behavioral symptom-management is not well developed in Japan. The purpose of this study was to examine the relationship between dementia status and burden of family caregivers in Japan.

2. Methods

2.1. Study design and subjects of Nagoya longitudinal study of frail elderly (NLS-FE)

The NLS-FE consisted of a cross-sectional analysis of a total of 1875 subjects (632 men and 1243 women). The details of the study were published elsewhere (Hirakawa et al., 2006a; Kuzuya et al., 2006). The study subjects were community-dwelling elderly persons (aged 65 years or older) eligible for public long-term care insurance, who lived in Nagoya city (Central Japan) and who were provided various home care services from the Nagoya City Health Care Service Foundation for Older People which comprises 17 visiting nursing stations and corresponding care-managing centers. During the registration period (1 November 2003 to 31 December 2003), 1875 out of 3630 elderly users agreed to take part in this study. Informed consent for participation was obtained verbally from the patients, or for those with substantial cognitive impairment, from a surrogate, and from the caregivers according to procedures approved by the institutional review board of the Nagoya University Graduate School of Medicine.

2.2. Data collection and instruments

A total of 56 nurses and 48 care-managers visited the users' homes and collected data from standardized interviews with patients or surrogates and caregivers as well as from medical and visiting nursing station records. The abstractors were blinded to the study hypothesis and anticipated study results. The data we used in this analysis included the following items about caregivers and dependents: dependent's age, gender, marital status, number of residents, nutrition method, degree of required care, behavioral disorder, activities of daily living (ADL) and illness, caregiver's age, gender, kinship, and public care service use.

The main outcome was subjective caregiver burden assessed by the J-ZBI, which is a 22-item self-report inventory that examines the burden associated with functional behavioral impairments in the home care situation (Arai et al., 1997).

The various comorbid conditions of dependents were recorded as present if documented in the visiting nursing station records. Severity of dementia was evaluated according to the criteria provided by the public long-term care insurance policy, which are classified into six levels (levels 0–5) (Onishi et al., 2005). ADL limitation was evaluated according to four ranks of ADL of disabled elderly, identified by the Japanese government as follows—rank J: independent in ADL; rank A: house-bound; rank B: chair-bound; and rank C: bed-bound (Hirakawa et al., 2005).

The Japanese long-term care system is a public, mandatory long-term care insurance for the frail elderly. The insurance system is financed through premiums from everyone aged 40 and older and government subsidy. Anyone aged 65 and older is eligible for benefits based strictly on physical and mental disability, in six levels of need ranging from "not applicable" to "5" (completely dependent on ADL).

2.3. Statistical analysis

We excluded from the present analysis those subjects whose diagnosis of dementia had not been confirmed. Consequently, a total of 1559 pairs of dependents and caregivers were included in the analysis. The pairs were sorted into three mutually exclusive categories: (1) no dementia; (2) mild dementia (levels 1–2), and (3) severe dementia (levels 3–4). Because level 5 includes severe cognitive impairment caused by severe physical ailments (Onishi et al., 2005), we excluded the dependents in level 5 from the present analysis. The differences in dependent and caregiver characteristics among the dementia categories were assessed using the chi-square test for categorical variables or the Kruskal–Wallis test for continuous variables. Multiple logistic regression was used to examine the link between severity of dementia and caregiver burden, adjusting for dependent age, sex, marital status, number of residents, nutrition, illness, ADL scale, caregiver age, sex, kinship, and care service use. The data was analyzed using Statview-J 5.0.

3. Results

3.1. Characteristics of dependents

The distribution of dependent characteristics is shown in Table 1. Two hundred sixty-one dependents had severe dementia, and 725 had mild dementia. Dependents with severe dementia were the oldest across the three dementia categories. Dependents with severe dementia were the most likely to be bereaved, have a larger number of residents, receive parenteral nutrition, have a higher degree of care level and a lower ADL. As for illness, dependents with severe dementia were the most likely to have cerebrovascular disease, hemiplegia, or pressure ulcer, and were the least likely to have connective tissue disease. Dependents with mild dementia were more likely to have hypertension than the other two categories.

Table 1
Differences in characteristics of the dependents by dementia category

Variables	No dementia (n = 573)	Mild dementia (n = 725)	Severe dementia (n = 261)	p
Age (year)	79.08 ± 7.62	81.70 ± 8.04	82.70 ± 8.26	<0.01
Sex				
Women	61.95	63.72	70.50	NS
Marital status				
Married	58.29	48.28	40.61	<0.01
Bereaved	39.62	48.55	57.85	
Divorced	0.35	1.79	0.00	
Not married	1.57	1.24	1.53	
Number of residents	1.84 ± 1.59	1.98 ± 1.49	2.27 ± 1.50	<0.01
Nutrition				
Peroral	99.13	97.52	87.36	<0.01
Parenteral	0.87	2.34	12.26	
Intravenous hyperalimentation	0.00	0.14	0.38	
Degree of care required				
Not applicable	0.17	0.14	0.00	<0.01
Assistance required	10.30	2.62	0.00	
Degree 1	36.82	24.97	4.60	
Degree 2	21.99	24.41	11.49	
Degree 3	14.31	18.48	19.16	
Degree 4	9.08	14.76	19.54	
Degree 5	6.98	14.62	44.44	
ADL scale of disabled elderly				
Independent	7.68	1.52	0.77	<0.01
J	26.88	19.03	6.13	
A	41.01	42.62	24.90	
B	17.80	24.00	29.50	
C	6.11	12.55	38.31	
Illness				
Ischemic heart disease	11.69	12.14	10.73	NS
Congestive heart failure	6.63	9.79	9.20	NS
Ulcer disease	1.22	1.66	2.30	NS
Peripheral vascular disease	2.09	3.17	1.92	NS
Liver disease	2.97	3.03	1.92	NS
Cerebrovascular disease	29.49	42.76	50.57	<0.01
Connective tissue disease	7.33	3.45	1.92	<0.01
Diabetes	14.14	14.34	15.33	NS
Chronic pulmonary disease	7.50	6.76	4.98	NS
Hemiplegia	26.53	25.52	36.02	<0.01
Renal failure	4.54	4.41	3.07	NS
Neoplasia	9.77	8.83	5.75	NS
Leukemia/lymphoma	0.17	0.00	0.00	NS
Metastatic solid tumor	0.70	0.28	0.00	NS
Hypertension	19.55	26.34	23.75	<0.05
Pressure ulcer	4.01	6.21	16.48	<0.01

Notes: Data are presented as the mean value ± S.D. or percentage of subjects. The chi-square test for categoric variables or the Kruskal–Wallis test for continuous variables was conducted among dementia groups.

Table 2

Differences in characteristics of the main caregiver by dementia category

Variables	No dementia ($n = 573$)	Mild dementia ($n = 725$)	Severe dementia ($n = 261$)	p
Age (year)	63.63 ± 12.98	64.20 ± 12.54	64.49 ± 11.41	NS
Sex				
Women	69.28	78.62	75.86	<0.01
Kinship	46.07	39.03	35.25	<0.01
Spouse	48.52	58.07	60.54	
Child (including daughter/son-in-law)	5.41	2.76	4.21	<0.05
Others				
Types of care service use				
Day care/service	33.86	54.90	57.09	<0.01
Home-visit rehabilitation	5.76	8.55	8.81	NS
Home-visit bathing	5.76	12.69	26.44	<0.01
Short stay	3.66	11.45	25.29	<0.01
Home help	46.60	38.34	37.55	<0.01
Family physician home-visit	51.83	64.28	66.67	<0.01
Home-visit nursing care	44.85	53.38	63.98	<0.01
Housing adjustments	27.05	24.41	19.54	NS
Care implements rental	58.99	62.62	72.80	<0.01

Notes: Data are presented as the mean value $\pm$ S.D. or percentage of subjects. The chi-square test for categoric variables or the Kruskal–Wallis test for continuous variables was conducted among dementia groups.

3.2. Differences in characteristics of caregivers and caregivers' burden

The distribution of caregiver characteristics is shown in Table 2. No statistical differences were found in age. In formal care services, caregivers of dependents with severe dementia were most likely to use day care/service, home-visit bathing, short stays, family physician home-visit, home-visit nursing care, or care implements rental, and least likely to use home help.

Table 3

Differences in caregiver burden of the main caregiver by dementia category

Categories	J-Zant	Unadjusted odds ratio	95% CI	Adjusted odds ratio[a]	95% CI	Adjusted odds ratio[b]	95% CI
No dementia	23.57 ± 16.62	1	–	1	–	1	–
Mild dementia	$29.6\ 4 \pm 16.36$	1.023	1.015–1.031	1.029	1.020–1.038	1.023	1.013–1.033
Severe dementia	35.51 ± 16.76	1.039	1.029–1.048	1.052	1.040–1.065	1.051	1.035–1.066

Notes: Data are presented as the mean value $\pm$ S.D.

[a] Adjusted for dependent factor (age, sex, marital status, number of residents, nutrition, and illness) and caregiver factor (age, sex, kinship, and care service use).

[b] Adjusted for dependent factor (age, sex, marital status, number of residents, nutrition, illness, and ADLs) and caregiver factor (age, sex, kinship, and care service use).

The multivariable-adjusted results of J-ZBI are shown in Table 3. Although differences were found among the dementia categories in levels of caregiver burden according to the J-ZBI before and after adjusting for these baseline variables, the odds-ratios nearly equal 1.

4. Discussion

The present study of a representative sample of community-dwelling elderly in Nagoya City shows that severity of dementia is not associated with caregiver burden. Although the link between severity of dementia and caregiver burden has not been studied extensively, it has been reported that caregiver burden for elderly patients with dementia is caused by different factors than for patients with other chronic illness, namely behavior disturbance or resistance to care (Coen et al., 1997; Donaldson et al., 1998; Asada et al., 1999; Hart et al., 2003). In addition, a number of studies have reported that behavioral problems cause fall-related injuries, which are also associated with caregiver burden (Asada et al., 1999; Kuzuya et al., 2006). Therefore, we hypothesized that demented elderly patients impose more caregiver burden on Japanese caregivers, especially severe demented patients with behavioral and psychological symptoms.

Consistent with a previous report, our study indicated that dementia was associated with significantly higher rates of ADL limitations. Because dementia has negative effects on the physical functioning of elderly patients, it seemed reasonable to assume that ADL limitations would be more prevalent among demented elderly dependents than among those without dementia. In addition, we found that demented dependents were more likely to suffer from cerebrovascular disease, hypertension, and pressure ulcer. It is well known that disease profiles are positively related to older age, dementia, or ADL limitations. In this respect, the fact that demented dependents were older or more likely to have a lower ADL level than non-dementia dependents may have influenced our study results.

In items of care services, use of day service, home-visit bathing, short stays, or family physician's or nurse's home visit were more prevalent among demented dependents, although non-nursing home help was less prevalent among them. The greater number of dependents having difficulty bathing among demented dependents may have contributed to the greater prevalence of home-visit bathing use among them. In addition, respite care such as short stays refers to any intervention designed to give rest or relief to caregivers. Some studies have suggested that respite care for demented persons living at home significantly reduces stress among caregivers (Conlin et al., 1992; Zarit et al., 1998; Lee and Cameron, 2004), and this may explain the greater prevalence of day service or short stay use among demented dependents. Although the greater prevalence of use of family physician's or nurse's home visit was expected and previously reported, the lower use of non-nursing home help was not reported. One good explanation for the lower use of home help is that caregivers of demented dependents gave other services such as nursing home visit priority over non-nursing home help.

Our results, regardless of adjustment, did not reveal clear differences among the dementia groups with respect to caregiver burden. As described previously, this finding differs from other studies, which suggest that caregivers of elderly with severe dementia showed more caregiver burden than caregivers of non-demented or mildly cognitively impaired