

### 3. 連携医療における問題点と課題

看護師は、様々な障害や疾患に関連して長い経過で疼痛を抱える患者に関わっている。外来においては、主に神経ブロックや検査の介助を通して、患者の安全安楽を図るように援助している。また、腰痛や肩部痛など筋骨格系障害に関連して入院している患者に対し、マッサージや電法など苦痛の軽減を図り、また、帯状疱疹後神経痛や幻肢痛に苦悩する患者に対し、その患者が置かれた状況に合わせて環境調整を工夫して、日常生活動作を援助している。しかし、疼痛治療が難渋する中で、必ずしもケアの方向性を明確にして、計画的にアプローチするまでには至っていないのが現状である。

最近、がん性疼痛に対しては、がん看護専門看護師<sup>13)</sup>、がん性疼痛看護認定看護師、緩和ケア認定看護師等が、緩和ケアチームのコーディネーターとなって、具体的に患者の疼痛緩和やQOLの向上に貢献している。慢性疼痛に対しても、その患者が体験している痛みを正確にアセスメントして、適切にアプローチする専門的な医療チームによる実践が望まれる。専門看護師と認定看護師は、医療現場において各々の役割を遂行し、患者・家族や他の医療職から認知され、評価されるようになって発展している。2007年4月施行の改正医療法により、専門性の広告が看護師に拡大され、一般市民の病院選択時の指標として「専門看護師と認定看護師の配置状況」が位置づけられることになった。認定看護師の目的は、「特定の看護分野において、熟練した看護技術と知識を用いて、水準の高い看護実践ができ、看護現場における看護ケアの広がりや質の向上を図る」ことにあり、現在、救急看護、皮膚・排泄ケア、集中ケア、緩和ケア、がん化学療法看護、がん性疼痛看護、訪問看護、感染管理、糖尿病看護、不妊症看護、新生児集中ケア、透析看護、手術看護、乳がん看護、摂食・嚥下障害看護、小児救急看護、認知症看護、脳卒中リハビリテーション看護の18領域が特定され、全領域で3,367名（2008年3月現在）が活躍している<sup>14)</sup>。この動向から考えると、慢性疼痛看護認定看護師を育成することが、看護領域における慢性疼痛の専門的な臨床実践の第一歩となるであろう。医師・理学療法士・作業療法士・臨床心理士・看護師等の専門家が共同して関わる interdisciplinary team<sup>15)</sup>が構成される時、看護師は複雑に要因が絡む慢性疼痛患者に対して専門的な視点で関わりと同時に、チームの潤滑油として有効に機能すると期待できる。

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# 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).<sup>1,2</sup> 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.<sup>2-4</sup> 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.<sup>5-7</sup> 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.<sup>8,9</sup> 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  $\geq 65$ ).

#### 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,<sup>10</sup> 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	Difficulty n = 1,091			P-Value
	No Difficulty n = 681	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 $\pm$ SD <sup>†</sup>	78.9 $\pm$ 6.8	81.4 $\pm$ 8.0	79.9 $\pm$ 7.6	<.001
Activities of daily living, mean $\pm$ SD (range 0–20) <sup>†</sup>	17.4 $\pm$ 3.0	9.2 $\pm$ 6.5	14.5 $\pm$ 4.6	<.001
Instrumental activities of daily living, mean $\pm$ SD (range 0–8) <sup>‡§</sup>	5.7 $\pm$ 1.5	1.4 $\pm$ 1.8	3.4 $\pm$ 1.7	<.001
Charlson Comorbidity Index, mean $\pm$ SD <sup>**</sup>	1.4 $\pm$ 1.4	2.5 $\pm$ 1.6	1.7 $\pm$ 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
$\geq$ 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.

<sup>†</sup> No difficulty versus having assistance,  $P < .001$ ; no difficulty versus no assistance,  $P = .34$ ; having assistance versus no assistance:  $P = .05$ .

<sup>‡</sup> No difficulty versus having assistance,  $P < .001$ ; no difficulty versus no assistance,  $P < .001$ ; having assistance versus no assistance,  $P < .001$ .

<sup>§</sup> 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

Mortality and Hospitalization	Difficulty with Self-Medication		
	Difficulty with Self-Medication	Receiving Assistance	Absence of Assistance
	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-

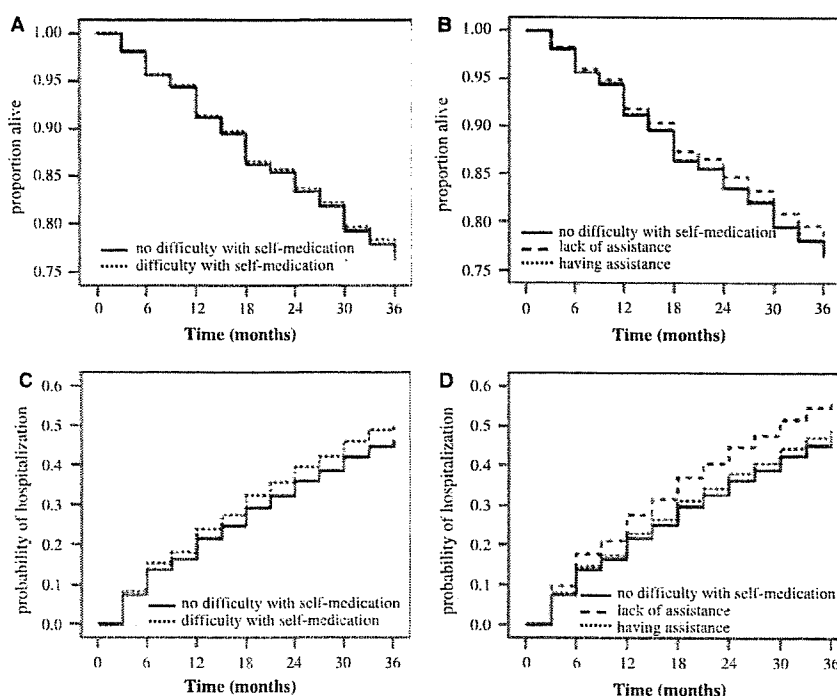


Figure 1. Multivariate adjusted Kaplan-Meier plots of survival (A, B) and hospitalization (C, D) during the 3-year follow-up in participants according to the presence or absence of difficulty with self-medication management, or receiving medication assistance. Gender, age, activities of daily living (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.<sup>11</sup> 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.<sup>12-14</sup> In addition, it has been reported that a high percentage of medication-related hospital admissions are due to poor medication adherence.<sup>13,15</sup> 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.<sup>16,17</sup> 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 LTCL 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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**Author Contributions:** Masafumi Kuzuya: study concept, design, conduct of study, interpretation of data, study supervision, and preparation of manuscript. Yoshihisa Hirakawa: conduct of study and interpretation of data. Yusuke Suzuki: analysis and interpretation of data. Mitsunaga Iwata: analysis and interpretation of data. Hiromi Enoki: statistical analysis and interpretation of data. Jun Hasegawa: acquisition of data. Akihisa Iguchi: study supervision.

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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.<sup>1,2</sup> 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,<sup>3</sup> although others have been unable to confirm this association.<sup>4</sup> 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)<sup>5,6</sup> 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  $\pm$  standard deviation  $80.4 \pm 7.9$ ) 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:  $\leq 67$  beats per minute (bpm), mean  $61.5 \pm 4.8$ ,  $n = 231$ ; Quartile 2: 68–72 bpm,  $70.8 \pm 1.6$ ,  $n = 265$ ; Quartile 3: 73–80 bpm,  $77.6 \pm 1.9$ ,  $n = 236$ ; Quartile 4:  $\geq 81$  bpm,  $88.1 \pm 6.2$ ,  $n = 200$ ). 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.<sup>1–3</sup> 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-

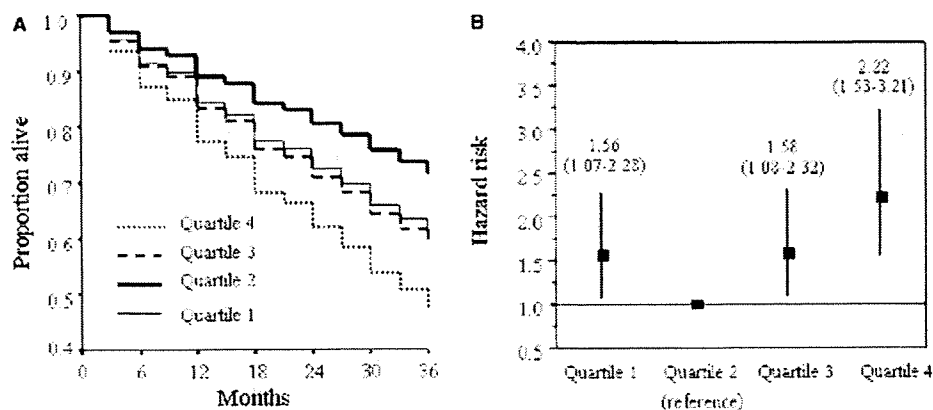


Figure 1. (A) Kaplan-Meier survival curves over the 3-year study period according to quartiles of baseline pulse rate ( $\leq 67$ , 68–71, 72–80,  $\geq 81$ ). Log rank test:  $P < .001$ . (B) Risk of death according to quartiles of pulse rate, adjusting for sex, age, activity of daily living score, 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),<sup>1</sup> 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.<sup>2,3</sup> 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.<sup>4</sup>

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,<sup>5</sup> lower estimated glomerular filtration rates,<sup>6</sup> 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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## 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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## 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 categorical 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 ± S.D. or percentage of subjects. The chi-square test for categorical 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 <sup>a</sup>	95% CI	Adjusted odds ratio <sup>b</sup>	95% CI
No dementia	23.57 ± 16.62	1	–	1	–	1	–
Mild dementia	29.64 ± 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 ± S.D.

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

<sup>b</sup> 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



dependents. There are two possible explanations for our results. First, in Japan, the number of group homes for patients with dementia, which are small home-style facilities covered by public long-term care insurance, has recently increased dramatically (Hirakawa et al., 2006c). Some demented elderly who require professional psychological support might give up living in a community setting and opt for a group home for patients with dementia instead. Second, according to the abstractor's assessment, 90% of the caregivers used sufficient formal care among the three dementia groups (data not shown in the tables). It is possible that the sufficiency of care lessened the dementia caregiver burden and narrowed the gap in caregiver burden between caregivers of dependents with dementia and without dementia. However, our database does not include informal dementia care by community, which is needed to obtain a precise analysis of the impact of the social situation on the caregiver burden of dementia. Future studies should examine how adequate stage-related intervention for dementia caregiving might reduce caregiver burden within the home.

The current study has several limitations. First, the NLS-FE does not include the complete spectrum of home elderly patients in the Nagoya area, because the participants were groups of users of home nursing stations using home visiting nurses or care planning services. Second, our database may not have captured the full extent of important measures that might influence the level of caregiver burden, including informal care-giving or community care. Lastly, the omission of detailed assessments of health or socio-demographic status among caregivers limits our study results, because caregiver characteristics are possibly associated with perceived caregiver burden.

## 5. Conclusion

We conducted a sub-analysis of a large-scale observational study in Japan. This study focused on differences in caregiver burden of the elderly according to dementia status in community settings. Our results indicated that there were no differences in caregiver burden between caregivers of dependents with dementia and without dementia.

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### INCREASED CAREGIVER BURDEN ASSOCIATED WITH HEARING IMPAIRMENT BUT NOT VISION IMPAIRMENT IN DISABLED COMMUNITY-DWELLING OLDER PEOPLE IN JAPAN

*To the Editor:* It has been demonstrated that older people feel that hearing and vision impairments are substantially disabling, that these impairments are associated with lower-than-average quality of life, and that they predict future loss of functional abilities and independence.<sup>1-5</sup> However, whether these sensory impairments add to the burden of caregivers of disabled older people living in the community has not been evaluated.

The present study examined the association between vision or hearing impairment in community-dwelling older people with disabilities and the subjective burden of their caregivers. The study used baseline data on care recipient and family caregiver pairs in the Nagoya Longitudinal Study for Frail Elderly.<sup>6,7</sup> The study population consisted of 1,208 community-dwelling older people (448 men and 760 women; mean age  $\pm$  standard deviation 80.9  $\pm$  7.8, range 65-104) and paired caregivers (286 men and 922 women; mean age 64.7  $\pm$  12.4, range 31-90). The baseline data included the recipients' demographic characteristics and basic activities of daily living (ADLs), physician-diagnosed chronic conditions including dementia, the presence of behavioral problems, living arrangement, and history of falls in the previous 6 months. Data were also obtained from caregivers concerning their own personal demographic characteristics, including caregiver relationship to care recipient, and the caregiver's subjective burden as assessed according to the Japanese version of the Zarit Burden Interview (ZBI),<sup>8</sup> which has an 88-point scale, with higher values indicating greater burden. The primary caregivers were also asked to rate their own current overall health in three categories of subjective health status. Recipients with vision or hearing impairment were identified according to a yes answer to the following question: "Do you have trouble seeing or hearing for daily life, even when wearing glasses or using a hearing aid?" When the recipients were unable to answer or had cognitive impairment, surrogates or caregivers were asked. The Student *t*-test and analysis of covariance (ANCOVA) were used to compare caregiver ZBI scores for recipients with and without sensory impairment. Covariates of ANCOVA included recipient sex, age, ADL score, presence or absence of dementia and behavior problems and caregiver sex, age, and subjective health status. To determine which variables were associated with ZBI score, a stepwise multiple linear regression analysis with a forward selection strategy was performed, using an *F* value with  $P < .05$  as the

**Table 1. Stepwise Multiple Linear Regression of Care Recipients' and Caregivers' Variables on Zarit Burden Interview Score**

Variable	B	Standard Error	$\beta$	P-Value
Care recipient sex male	-2.610	1.063	-0.074	.01
Care recipient age	-0.181	0.072	-0.081	.01
ADL score (range 0-20)	-0.521	0.090	-0.176	<.001
Fall in previous 6 months	2.852	1.065	0.079	.008
Presence of behavioral problems	8.402	1.464	0.197	<.001
Presence of dementia	3.622	1.242	0.103	.004
Hearing impairment	3.645	1.160	0.100	.002
Health status of caregiver	3.344	0.773	0.130	<.001

Coefficient of determination ( $R^2$ ) = 0.176; adjusted  $R^2$  = 0.170.

The following variables were added to the analysis: care recipient age and sex, fall history in the previous 6 months, living arrangement, activity of daily living (ADL) scores, presence of dementia and behavioral problems, number of community-based services used, age and sex of caregiver, type of caregiver-care recipient relationship (spouse, child, daughter-in-law), and subjective health status of caregiver.

selection criterion. All analyses were performed using SPSS version 16.0 (SPSS, Inc., Chicago, IL).

Of the care recipient participants, 334 (28.5%) had vision impairment and 387 (32.1%) had hearing impairment. Participants with impairment in vision or hearing were older on average. Although no difference in average caregiver ZBI score was observed between recipients with and without vision impairment (with vision impairment mean  $\pm$  standard error, 29.8  $\pm$  0.9; without 28.4  $\pm$  0.6,  $P = .22$  on Student *t*-test), a significantly higher average caregiver ZBI score was detected for recipients with hearing impairment than for those without (with hearing impairment, 31.3  $\pm$  0.9; without 27.8  $\pm$  0.6,  $P < .001$ ). This statistical significance persisted even after adjusting for confounders (ANCOVA, with hearing impairment, 31.6  $\pm$  0.9; without 27.4  $\pm$  0.6,  $P < .001$ ).

The stepwise multiple regression analyses revealed that the best set of predictors of caregiver burden was recipient sex, age, ADL score, fall history in the previous 6 months, presence or absence of dementia and behavioral problems associated with dementia, and hearing status and health status of caregiver (Table 1).

The present study demonstrated for the first time that hearing impairment of elderly care recipients is associated with greater caregiver burden. This association persists even after controlling for various possible confounding factors such as ADL status and the presence of chronic diseases, including dementia. However, vision impairment of recipients was not associated with caregiver burden. It has been reported that caregivers who desired more communication with patients had significantly higher caregiver burden scores than did caregivers who did not.<sup>9</sup> It is possible that hearing impairment of care recipients may affect recipient-caregiver communication more strongly than vision impairment.

There are potential limitations in this study. Hearing ability and visual activity were not evaluated using audiometry or direct measurement of visual acuity. Therefore, the evaluation of impairments may not be accurate. The present 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 the cost of health care may have influenced these results.

In conclusion, these results suggest that hearing impairment of care recipient is associated with caregiver burden in Japan, even after adjusting for potential confounders. It is possible that improvement in hearing or correcting hearing impairment may lead to reduced caregiver burden.

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## STROKE IN ELDERLY PEOPLE: A GREAT CHALLENGE FOR THE 21ST CENTURY

*To the Editor:* The recent population-based epidemiological studies covering the end of the 20th and the beginning of the 21st centuries have largely contributed to emphasizing the

burden of stroke in elderly people in developed countries.<sup>1-3</sup> Their findings have provided clear evidence of a dramatic increase in the absolute number of cerebrovascular events in people aged 80 and older over the last past 20 years due to the aging of the population of these countries. Hence, the profile of patients admitted to stroke units and emergency departments has changed considerably, because the mean age at stroke onset is now significantly older than in the past.<sup>1-3</sup> Nevertheless, randomized clinical trials conducted so far have systematically excluded elderly people from enrollment. As a result, these patients have been denied the opportunity to benefit from therapeutic strategies, including thrombolysis, whose efficacy in reducing mortality and handicap after ischemic stroke has been demonstrated in younger patients.<sup>4</sup> Consequently, for physicians, there is currently a lack information concerning evidence-based acute therapeutic strategies to use in patients aged 80 and older in day-to-day practice of vascular neurology. The problem is similar for secondary prevention, which is consequently limited in this age group, particularly concerning the use of anticoagulants in elderly patients with stroke with atrial fibrillation.

The absence of such strategies is alarming, given that demographic projections clearly indicate that the number of elderly people is expected to increase. Hence, in Europe, the proportion of the population aged 65 and older, in which most stroke events occur, will increase from 20% in 2000 to 35% in 2050, leading to continued growth in the number of older stroke patients in the community.<sup>5</sup> Therefore, the improvement in stroke outcome observed between the end of the 20th century and the beginning of the 21st,<sup>3</sup> which is related, at least in part, to better acute management of patients, will probably be rapidly annihilated if elderly people continue to be excluded from large randomized trials. Furthermore, such a scenario would inevitably be associated with a considerable socioeconomic effect, because older stroke patients have a longer hospital stay and are less likely to be discharged to their original place of residence.<sup>6</sup>

Epidemiological studies have played their role by pointing out the threat of the increasing burden on health-care systems of stroke in elderly people. It is now essential and urgent for scientists to design new clinical trials recruiting patients aged 80 and older to provide the means to respond to this demographic evolution.

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