

Table 3 Mean values (standard deviation) of 6-m walking time (s) and walking speed (m/s) with usual pace and the fastest pace classified by age and gender

Age strata (years)	Number of subjects	Usual pace		Fastest pace	
		Time for 6 m (s)	Walking speed (m/s)	Time for 6 m (s)	Walking speed (m/s)
Men					
40–49	32	4.4 (0.6)	1.38 (0.19)	3.0 (0.5)	2.09 (0.43)
50–59	100	4.8 (0.9)	1.29 (0.20)	3.2 (0.6)	1.97 (0.36)
60–69	134	5.1 (0.9)	1.21 (0.20) ^a	3.4 (0.7)	1.82 (0.33) ^a
70–79	196	5.9 (1.8) ^{a,b,c}	1.09 (0.25) ^{a,b,c}	4.0 (1.4) ^{a,b,c}	1.62 (0.39) ^{a,b,c}
80 and older	97	6.8 (3.0) ^{a,b,c,d}	0.99 (0.33) ^{a,b,c,d}	4.5 (1.8) ^{a,b,c,d}	1.48 (0.44) ^{a,b,c}
Total	559	5.6 (1.9)	1.15 (0.27)	3.7 (1.3)	1.73 (0.42)
Women					
40–49	92	4.7 (1.0)	1.32 (0.24)	3.2 (0.6)	1.95 (0.31)
50–59	190	4.9 (0.9)	1.27 (0.23)	3.3 (0.7)	1.87 (0.33)
60–69	299	5.1 (1.1)	1.22 (0.23)	3.7 (0.8)	1.71 (0.32) ^{a,b}
70–79	345	6.3 (2.4) ^{a,b,c}	1.03 (0.25) ^{a,b,c}	4.4 (1.5) ^{a,b,c}	1.46 (0.36) ^{a,b,c}
80 and older	152	8.4 (3.9) ^{a,b,c,d}	0.82 (0.27) ^{a,b,c,d}	5.8 (2.7) ^{a,b,c,d}	1.17 (0.36) ^{a,b,c,d}
Total	1,078	5.9 (2.4)	1.12 (0.29)	4.1 (1.6)	1.60 (0.42)

^a Significantly different ($p < 0.05$) from values of the age group in their 40s

^b Significantly different ($p < 0.05$) from values of the age group in their 50s

^c Significantly different ($p < 0.05$) from values of the age group in their 60s

^d Significantly different ($p < 0.05$) from values of the age group in their 70s

Table 4 Values of median (25–75 percentile) of one-leg standing time (s, maximum = 60 s) in a better side and a worse side classified by age and gender

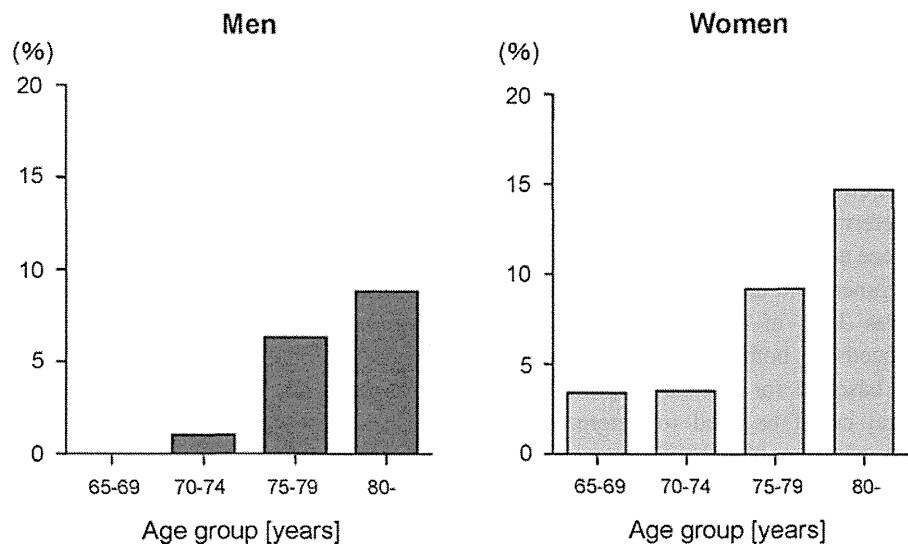
Age strata (years)	Number of subjects	One-leg standing time (better side) (s)	One-leg standing time (worse side) (s)
Men			
40–49	32	60 (60–60)	60 (60–60)
50–59	99	60 (60–60)	60 (60–60)
60–69	136	60 (34.5–60)	45 (14.25–60)
70–79	303	27 (9–60)	9 (4–35)
80 and older	246	8 (4–32)	4 (2–12)
Total	816	39.5 (8–30)	14 (4–60)
Women			
40–49	92	60 (60–60)	60 (60–60)
50–59	191	60 (60–60)	60 (43–60)
60–69	317	60 (41.5–60)	43 (13–60)
70–79	593	21 (8–57.5)	8 (3–25)
80 and older	424	7 (3–18.8)	3 (2–7)
Total	1,617	31 (8–60)	12 (4–60)

pace [+1 s, odds ratio (OR) 1.15, 95% confidential interval (CI) 1.07–1.24, $p < 0.001$] and at the fastest pace (+1 s, OR 1.22, 95% CI 1.08–1.38, $p < 0.01$). In addition, there were significant associations between the presence of disability and walking speed at the usual pace (+1 m/s, OR 0.07, 95% CI 0.02–0.27, $p < 0.001$) and at the fastest pace (+1 m/s, OR 0.16, 95% CI 0.06–0.41, $p < 0.001$).

Discussion

In this study, we established age-gender-classified mean values for hand grip strength as an index of muscle strength, muscle mass as an index of muscle volume, and walking time and median one-leg standing time as indices of physical performance, using data for a large-scale

Fig. 1 Prevalence of disability among subjects ≥ 65 years old classified by gender and age



population-based cohort. We found that mean hand grip strength, muscle mass, walking time, and median one-leg standing time were higher in men than in women, and decreased with age (with the exception of the muscle mass of the lower legs).

The Japanese Ministry of Education, Culture, Sports, Science, and Technology has reported ranges for physical strength and sporting ability in 69,745 Japanese men and women 6–79 years old. Mean hand grip strength in both men and women reaches peak values between the ages of 20–40, and decreases with age after 40 [12]. In the present study of a population aged ≥ 40 years, hand grip strength declined significantly with age, consistent with the previous report of the Japanese government.

Although computed tomography or MRI scans are the most reliable methods of measuring segmental muscle mass, these methods are not suitable for a large-scale population-based study. The BIA method is rapid, inexpensive, portable, and importantly, a noninvasive measuring method. Previous studies have shown that there is a strong correlation between BIA resistance and measurements of skeletal muscle mass in the arms [13], legs [13], and whole body [14]. For the BIA method used in the present study, Miyatani et al. [10] had previously compared values for muscle mass using a series of cross-sectional images of the forearm, upper arm, lower leg, and thigh on the right side of 22 male subjects as determined by the BIA and MRI methods. The BIA impedance index (L^2/Z) for every segment, calculated as the ratio of the segment length squared to the impedance, was significantly correlated with the muscle volume measured by MRI, with $r = 0.902$ – 0.976 ($p < 0.05$). These previous results demonstrate that the BIA method used in the present study is sufficiently reliable as an index of muscle volume.

In the present study, age-related differences were observed in the thighs and quadriceps. In addition, the age-related decreases in muscle mass were greater in the lower limbs than in the upper limbs, and in proximal sites than in distal sites. Yamada et al. [15] estimated the bioelectrical impedance (BI) index, calculated as the ratio of the square of segmental length to impedance in a Japanese population consisting of 1,006 individuals (374 men, 632 women) and reported that the BI index decreased most with age in the thighs, whereas there were no significant age-related changes in the forearms or lower limbs. Miyatani et al. [16] studied muscle thickness at nine sites, the forearm, anterior and posterior upper arm, abdomen, subscapular, anterior and posterior thigh, and anterior and posterior lower leg, using brightness-mode ultrasonography in 348 Japanese men aged 20–79 years. They found a greater decrease in muscle thickness in the trunk and anterior thigh than at other sites, consistent with our results. They speculated that site-related differences in muscle loss with aging may be attributed to age-related changes in the patterns of loading to and/or activation of individual muscles in daily life. However, because these results were obtained from a cross-sectional study, longitudinal data would be required to determine the mechanism of these differences. We have begun the third visit of the ROAD study, 6 years after the baseline and 3 years after the second visit, to measure losses of skeletal muscle mass at various sites. Losses of muscle mass in the quadriceps and/or thighs may result in a decrease in walking ability, including walking speed. Therefore, establishment of reference values for muscle mass is useful for prediction of future disability.

Walking ability is regarded as the most important activity for the elderly to maintain an independent life in the community, and walking speed is an important index of

walking ability. Reference values have been published for populations in western countries [17, 18]; however, there has been little information available for the Japanese population. Takahashi et al. [19] surveyed walking speed at 130 crosswalks and reported that at least 1.0 m/s was required to safely cross the street. In the present study, we determined that the mean 6-m walking time at the usual pace at an age of ≥ 40 years was 5.6 s for men and 5.9 s for women, and the mean 6-m walking time at the fastest pace was 3.7 s in men and 4.1 s in women. These walking speeds for both the usual pace and the fastest pace provide a baseline for clinical judgments of patient performance and could be used to determine which subjects would benefit from therapeutic intervention to improve locomotive function.

The Japanese Ministry of Education, Culture, Sports, Science and Technology published mean values for one-leg standing time with a maximum time of 120 s using 5,500 individuals (2,741 men, 2,759 women) with an age range of 65–79 years in each prefecture who participated in an examination of sporting ability, including walking ability [12]. They reported that mean one-leg standing times for men 65–69, 70–74, and 75–79 years old were 79.9, 66.5, and 50.5 s, respectively, and those for women were 80.8, 62.1, and 45.0 s, respectively. These values were measured up to 120 s, and ours were measured up to 60 s. Because the measuring method was different and their outcomes are means while our results are medians, the results cannot be compared directly. However, one-leg standing time was significantly lower with age in both studies. Again, establishment of reference values for physical performance, including walking and standing ability, would be useful for prediction of future disability.

We then evaluated associations between hand grip strength, muscle mass, walking time, and one-leg standing time, as indices reflecting components of locomotive syndrome and the presence of disability. We found that the 6-m walking time may be a useful index for detection of disability. To evaluate the independence of elderly persons in daily life, physical performance has been measured using various outcomes. Walking speed has been reported to be one important index that can predict future disability, hospitalisation, and mortality in the general geriatric population [20, 21]. In a Japanese population, Shinkai et al. [22] demonstrated that lower scores on baseline performance measures, particularly maximum walking speed, predicted an increased risk of onset of functional dependence, based on their 6-year follow-up of a cohort in a rural community consisting of 736 participants. In the present study, a 1-s slower normal walking time for 6 m was associated with a 15% increase in the presence of disability, and a 1-s slower fastest walking time for 6-m was associated with a 22% increase in the presence of disability. Our study evaluated

only walking ability and the presence of disability, not the occurrence of disability; however, we expect to follow these populations and clarify the predictive ability of walking speed for the occurrence of disability over the next few years.

On the other hand, no associations were found between indices such as hand grip strength, muscle mass, and one-leg standing time and the presence of disability. There is growing evidence that reduced hand grip strength is associated with adverse outcomes in older years, including morbidity, lower quality of life, higher fracture rates, increased length of hospital stay, and mortality [23–25]. Progressive decline in muscle mass has been defined as sarcopenia, which represents an impaired state of health associated with morbidity disorders, increased risk of falls and fractures, impaired ADL, loss of independence, and increased risk of death [6, 26–29]. Lang et al. [29] stated that loss of muscle mass and power increases the difficulties associated with procuring adequate nutrition and the effort required to undertake exercise; the combination of nutritional loss and reduced physical activity levels results in further loss of muscle mass and power. The resulting decrements in power, endurance, and physical performance lead to a loss of independence. In addition to muscle strength and mass, balance appears to be an important index of disability. Shinkai et al. [22] measured the one-leg standing time of 736 participants in a cohort established in a rural community, and the individuals in the lowest performance quartile had a significantly higher occurrence of disability.

Self-selection bias is suggested as a possible reason for the lack of associations between hand grip strength, muscle mass, and one-leg standing time and disability observed here, compared with previous reports. Self-selection bias is one type of sampling bias exhibited by subjects who voluntarily enrol in an epidemiological study. In this second visit of the ROAD study, volunteers who could walk to the clinic where the survey was performed, and could understand and sign an informed consent form, and who wanted to learn about their bone and joint conditions were welcomed. Therefore, the participants in the second survey may have been healthier than the general Japanese population. In fact, the estimated number of persons with disability in Japan using the age-gender prevalence of the second visit and the age-gender distribution of the Japanese population based on the national census in 2007 would be estimated at 1,510,000 (350,000 men, 1,160,000 women), considerably lower than the 4,940,000 reported by the government in 2010. Thus, self-selection bias likely affected the reference values; the reference values for hand grip strength, muscle mass, and one-leg standing time obtained from the present study may be higher, and walking speed faster, than the actual values. However, self-selection bias is somewhat unavoidable in such an

examination, because it is impossible to obtain measurements for individuals who cannot grasp a handgrip dynamometer or walk 6 m. This bias should be taken into consideration when reference values are used, including not only those obtained from the present study, but also from the national survey of physical strength and sporting ability published by the government.

In addition to self-selection bias, this study has several limitations. First, our results were obtained from a cross-sectional study of the second visit of the ROAD study; thus, we can not conclude causal relationships between such indices and disability, since some of the indices, such as muscle mass and one-leg standing time, were first introduced and performed during the second visit. We have begun the third visit of the ROAD study to clarify the relationships between physical performance and the occurrence of disability. Once the significance of indices reflecting components of locomotive syndrome can be determined as predictors for the occurrence of disability, appropriate thresholds can be developed as predictors of future disability. In addition, because of the lack of sufficient information, we could not determine the disorders that caused the disability. Thus, the disabled status of the participants in the present study might have been affected by various diseases such as cardiovascular diseases, dementia, or other diseases. However, regardless of the cause of disability, we found that walking ability was significantly associated with the presence of disability.

Conclusions

We have established reference values for hand grip strength, muscle mass, walking time, and one-leg standing time using data for a large-scale population-based cohort, and identified gender and age differences in the reference values. In addition, we determined that walking ability, including walking time and walking speed at the usual and maximum pace, was significantly associated with the presence of disability.

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Conflict of interest No conflict of interest has been declared by the authors.

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ORIGINAL ARTICLE: SOCIAL RESEARCH,
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Incidence of certified need of care in the long-term care insurance system and its risk factors in the elderly of Japanese population-based cohorts: The ROAD study

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Aim: To examine the incidence of certified need of care in the national long-term care insurance (LTCI) system, and to determine its risk factors in the elderly of Japanese population-based cohorts of the Research on Osteoarthritis/Osteoporosis Against Disability (ROAD) study.

Methods: Of the 3040 participants in the baseline examination of the ROAD study, we enrolled 1773 (699 men, 1074 women) aged 65 years or older who were not certified as in need of care level elderly at baseline. Participants were followed for incident certification of need of care in the LTCI system. Associated factors in the baseline examination with occurrence were determined by multivariate Cox proportional hazards regression analysis. Muscle dysfunction was defined in accordance with the European Working Group on Sarcopenia in Older People algorithm for screening sarcopenia.

Results: A total of 54 men and 115 women were certified as in need of care level elderly during the average 4.0-year follow up. The incidence was 2.0 and 2.5 per 100 person-years in men and women, respectively. Identified risk factors were region, age, body mass index <18.5 or ≥27.5 kg/m², grip strength, knee extension torque, usual gait speed, chair stand time and muscle dysfunction.

Conclusions: Both underweight and obesity, as well as low muscle strength and physical ability, are risk factors for certification of need of care. Considering muscle dysfunction is a risk factor for occurrence, screened individuals are recommended to receive early intervention programs regardless of muscle volume. *Geriatr Gerontol Int* 2013; ●●: ●●-●●.

Keywords: activities of daily living, certification of need of care (*youkaigo-nintei*), disability, long-term care insurance system, prospective cohort study.

Introduction

Japan is a super-aged society experiencing an unprecedented aging of the population. The proportion of the population aged 65 years or older was 23% in 2010, and

is expected to reach 30.1% in 2024 and 39% in 2051.¹ This leads to an increasing proportion of disabled elderly requiring support or long-term care, imposing enormous economic and social burdens on the country. The Japanese Government started the national long-term care insurance (LTCI) system in 2000 based on the Long-Term Care Insurance Act.² The aim was to certify need of care level elderly, and to provide suitable care services according to the level of care required (seven levels, including requiring support [levels 1 and 2] and requiring long-term care [levels 1–5]). The total number of certified in need of care level elderly was reported to be 5 million in 2011.²

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Certification of need of care in the national LTCI system is an important outcome in Japan, not only because of its massive social and economic burdens, but also because it is urgently required to reduce its risk and decrease the number of disabled elderly requiring care in their activities of daily living (ADL). For establishment of an evidence-based prevention strategy, it is critically important to accumulate epidemiological evidence including the incidence of certified need of care and identification of risk factors. However, there have been no studies to clarify the incidence of certified need of care in the LTCI system or its risk factors using large-scale, population-based cohorts.

In 2005, we started a large-scale, population-based cohort study entitled the Research on Osteoarthritis/Osteoporosis Against Disability (ROAD) study with a total of 3040 participants, which aims to elucidate the environmental and genetic backgrounds of musculoskeletal diseases.^{3,4} The present study investigated the incidence of certified need of care in the national LTCI system, and determined its risk factors using a database from the ROAD study.

Methods

Participants

The present analysis was based on data collected from cohorts established in 2005 for the ROAD study. Details of the cohorts have been reported elsewhere.^{3,4} Briefly, we created a baseline database from 2005–2007, which included clinical and genetic information on 3040 residents of Japan (1061 men, 1979 women). Participants were recruited from resident registration listings in three communities, namely, an urban region in Itabashi, Tokyo, and rural regions in Hidakagawa and Taiji, Wakayama. Participants in the urban region in Itabashi were recruited from those of a cohort study,⁵ in which participants were randomly drawn from the register database of Itabashi ward residents, with a response rate of 75.6% in the group aged >60 years. Participants in the rural regions in Hidakagawa and Taiji were recruited from resident registration lists, with response rates of 68.4% and 29.3%, respectively, in the groups aged >60 years. Inclusion criteria were the ability to: (i) walk to the survey site; (ii) report data; and (iii) understand and sign an informed consent form. For the present study, we enrolled 1773 participants (699 men, 1074 women; mean age 75.4 years) aged 65 years or older who were not certified as need of care level elderly in the national LTCI system at baseline. All participants provided written informed consent, and the study was carried out with approval from the ethics committees of the University of Tokyo and the Tokyo Metropolitan Institute of Gerontology.

Baseline procedures

Participants completed an interviewer-administered questionnaire containing 400 items that included lifestyle information, such as smoking habits, alcohol consumption and physical activity. At baseline, anthropometric measurements, including height and weight, were taken, and body mass index (BMI; weight [kg]/height² [m²]) was estimated based on the measured height and weight. Underweight was defined as BMI <18.5 and obesity as BMI ≥27.5, according to the 2004 consensus statement from the WHO regarding appropriate BMI for Asian populations.⁶ Grip strength was measured on bilateral sides using a handgrip dynamometer (TOEI LIGHT, Saitama, Japan); the higher measurement was recorded. Isometric peak knee extension torque was measured at a knee flexion angle of 90° using a dynamometer (GT-30; OG GIKEN, Okayama, Japan) twice in participants from the urban regional cohort (Itabashi, Tokyo); the higher measurement was recorded. The time taken to walk 6 m at usual walking speed in a hallway was recorded, and usual gait speed was calculated. Skeletal muscle dysfunction was defined as usual gait speed ≤0.8 m/s or grip strength <30 kg in men and <20 kg in women, according to the algorithm for screening sarcopenia recommended by the European Working Group on Sarcopenia in Older People (EWGSOP).^{7,8} The time taken for five consecutive chair rises without the use of hands was recorded in the rural regional cohorts (Hidakagawa and Taiji, Wakayama). Hands were folded in front of the chest with feet flat on the floor. Timing began with the command “Go”, and ended when the buttocks contacted the chair on the fifth landing.

Certification of need of care in the LTCI system

The nationally uniform criteria for long-term care need certification was established objectively by the Japanese Government, and certification of need of care level elderly is determined based on evaluation results by the Certification Committee for Long-term Care Need in municipalities in accordance with basic guidelines formulated by the Government. The process of eligibility for certification of need of care in the LTCI system was described in detail by Chen *et al.*⁹ An elderly person who requires help with ADL or the caregiver contacts the municipal Government to request official certification of care needs. After the application, a trained official visits the home to assess the current physical status of the elderly person, including the presence or absence of muscle weakness or joint contracture of limbs, and difficulties in sitting-up, standing-up, maintaining sitting or standing position, transferring from one place to another, standing on one leg, walking, bathing, dressing, and other ADL. Mental status, including dementia, is also assessed. These data are analyzed to calculate a

Table 1 Baseline characteristics of population at risk for certified need of care in the long-term care insurance system

	Entire cohort		Urban cohort		Rural cohort	
	Men	Women	Men	Women	Men	Women
No. participants	699	1,074	333	486	366	588
Age (years)	75.6 (5.1)	75.2 (5.3)	77.5 (3.7)	77.3 (3.8)	73.8 (5.5) [†]	73.5 (5.8) [†]
Height (cm)	160.9 (6.0)	147.9 (6.0)*	161.0 (5.8)	148.2 (5.4)*	160.8 (6.2)	147.7 (6.5)*
Weight (kg)	59.4 (9.1)	50.0 (8.3)*	59.4 (8.2)	49.8 (7.8)*	59.4 (9.9)	50.1 (8.8)*
BMI (kg/m ²)	22.9 (2.9)	22.8 (3.4)	22.9 (2.7)	22.7 (3.3)	22.9 (3.1)	22.9 (3.5)
BMI <18.5 (%)	6.2	8.0	6.1	7.9	6.3	8.0
BMI ≥27.5 (%)	5.7	9.3**	3.9	8.5**	7.4	9.9
Grip strength (kg)	30.4 (6.8)	19.4 (4.9)*	28.6 (6.1)	18.2 (4.1)*	31.9 (7.0) [†]	20.3 (5.2)* [†]
Knee extension torque (kgm)	–	–	79.6 (27.2)	54.8 (17.0)*	–	–
Usual gait speed (m/s)	1.17 (0.31)	1.10 (0.33)*	1.27 (0.24)	1.22 (0.24)*	1.08 (0.34) [†]	1.00 (0.36)* [†]
Chair stand time (s)	–	–	–	–	10.8 (3.7)	12.2 (5.4)*
Muscle dysfunction (%) [§]	48.7	56.0**	52.6	60.0**	45.2	52.6***
Smoking (%)	21.0	3.2**	19.2	3.0**	22.6	3.4**
Alcohol consumption (%)	61.2	23.0**	61.0	28.8**	61.3	18.4***

Except where indicated otherwise, values are mean (SD). * $P < 0.05$ versus men in the corresponding group of the same cohort by unpaired Student's t -test. ** $P < 0.05$ versus men in the corresponding group of the same cohort by χ^2 -test. [†] $P < 0.05$ versus urban cohort in the corresponding group of the same sex by unpaired Student's t -test. [‡] $P < 0.05$ versus urban cohort in the corresponding group of the same sex by χ^2 -test. [§]Muscle dysfunction was defined as usual gait speed ≤ 0.8 m/s or grip strength < 30 kg in men and < 20 kg in women. BMI, body mass index; LTCI, long-term care insurance system.

standardized score for determination of the level of care needs (certified support, levels 1–2; or long-term care, levels 1–5). In addition, the primary physician of the applicant assesses physical and mental status, including information on diseases causing ADL disability and the extent of disabilities caused by them. Finally, the Certification Committee for Long-term Care Need reviews the data and determines the certification and its level.

Follow up and definition of incident certified need of care

After the baseline ROAD survey, participants who were not certified as need of care level elderly at baseline were followed for incident certification of need of care in the LTCI system. Incident certified need of care was defined as the incident certified 7 level, including requiring support (levels 1–2) and requiring long-term care (levels 1–5). Information on the presence or absence of certification of need of care and its date of occurrence were collected by the resident registration listings in three communities every year up to 2010, and were used for analyses in the present study.

Statistical analysis

All statistical analyses were carried out using STATA statistical software (STATA, College Station, TX, USA).

Differences in the values of the parameters between two groups were tested for significance using the non-paired Student's t -test and χ^2 -test. Factors associated with occurrence of certified need of care were determined using Cox proportional hazards regression analysis; hazard ratios (HR) and 95% confidence intervals (CI) were determined after adjusting for region, age, sex, and BMI.

Results

Of the 1773 participants who were not certified as in need of care level elderly at baseline, information on certification of need of care could be obtained in 1760 (99.3%) during the average 4.0-year follow up. A total of 54 men and 115 women were certified as in need of care level elderly in the national LTCI system; whereas, 1591 remained uncertified during the follow-up period. A total of 126 participants died, and eight moved away.

Table 1 shows the baseline characteristics of the population at risk for occurrence of certified need of care in the LTCI system. Although BMI was not significantly different between men and women in the entire, urban or rural cohorts, prevalence of obesity (BMI ≥ 27.5) was significantly higher in women than in men in the entire and urban cohorts. The prevalence of underweight was higher in women than in men in the entire,

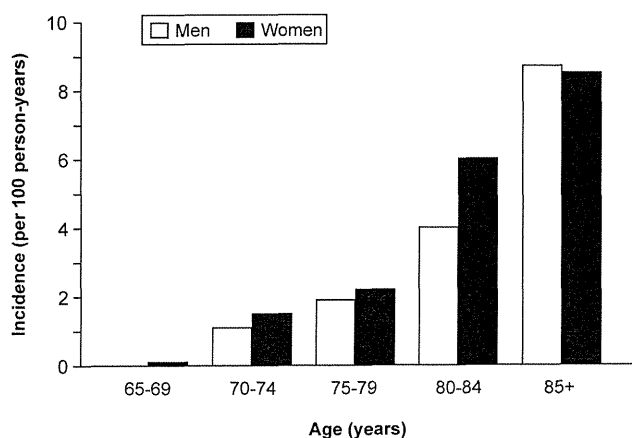


Figure 1 Incidence of certified need of care in the long-term care insurance system in men and women in each age stratum.

urban and rural cohorts; however, there was no significant difference. The prevalence of skeletal muscle dysfunction, determined by gait speed and grip strength, was significantly higher in women than in men in the entire, urban and rural cohorts.

Figure 1 shows sex- and age-distributions of the incidence of certified need of care in the LTCI system. Incidence was 2.3/100 person-years in the overall population of the entire cohort, and 2.0/100 person-years in men and 2.5/100 person-years in women. The incidence was very low in the age-stratum of 65–69 years, whereas, it tended to be markedly higher in the age-strata of 80 years and older in both sexes.

We then determined the risk factors for occurrence of certified need of care in the LTCI system. First, analysis was carried out using region, age, sex and BMI as explanatory variables in the Cox proportional hazards regression model (upper part of Table 2). Rural region and age were found to be risk factors for occurrence of certified need of care in the overall population. Sex and BMI were not significantly different. To further investigate the association between BMI and occurrence, we categorized BMI into three groups. Both underweight (BMI <18.5) and obesity (BMI ≥27.5) were found to be risk factors for occurrence of certified need of care, showing a U-shaped association. As for muscle strength and physical performance, handgrip strength, knee extension torque, usual gait speed, chair stand time and muscle dysfunction were found to be significantly associated with occurrence of certified need of care (lower part of Table 2). We carried out the same analyses in men and women separately (Table 2), and found results similar to those of the overall population.

Discussion

The present study investigated the incidence of certified need of care in the national LTCI system, and

Table 2 Hazard ratios and 95% confidence intervals for occurrence of certified need of care in the long-term care insurance system

	Overall population		Men		Women	
	Crude HR (95% CI)	Adjusted HR (95% CI)	Crude HR (95% CI)	Adjusted HR (95% CI)	Crude HR (95% CI)	Adjusted HR (95% CI)
Region (rural vs urban)	1.15 (0.83–1.59)	1.61 (1.17–2.24) ^b	1.13 (0.65–1.96)	1.64 (0.94–2.86) ^g	1.15 (0.77–1.72)	1.59 (1.07–2.38) ^g
Age (+1 year)	1.17 (1.13–1.20)	1.17 (1.14–1.21) ^c	1.19 (1.12–1.26)	1.19 (1.13–1.26) ^h	1.16 (1.12–1.20)	1.16 (1.12–1.21) ^h
Sex (women vs men)	1.25 (0.90–1.74)	1.24 (0.89–1.73) ^d	–	–	–	–
BMI (+1 kg/m ²)	0.98 (0.93–1.03)	1.01 (0.96–1.06) ^e	0.93 (0.84–1.02)	0.96 (0.88–1.06) ⁱ	1.00 (0.94–1.06) ^j	1.02 (0.97–1.08) ^j
≥18.5 or <27.5	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)
BMI <18.5	2.10 (1.31–3.38)	1.77 (1.10–2.84) ^e	2.43 (1.09–5.40)	1.69 (0.75–3.82) ⁱ	1.93 (1.07–3.48)	1.79 (0.99–3.22) ⁱ
BMI ≥27.5	1.82 (1.13–2.93)	2.12 (1.32–3.43) ^e	1.39 (0.50–3.87)	1.91 (0.68–5.38) ⁱ	1.92 (1.12–3.29)	2.18 (1.27–3.75) ⁱ
Grip strength (+1 kg)	0.93 (0.91–0.95)	0.94 (0.91–0.97) ^f	0.91 (0.87–0.95)	0.94 (0.89–0.99) ^j	0.89 (0.85–0.92)	0.94 (0.89–0.98) ^j
Knee extension torque (+1 kgm)	0.97 (0.96–0.99)	0.97 (0.96–0.99) ^f	0.97 (0.95–0.99)	0.97 (0.95–0.99) ^j	0.97 (0.95–0.99)	0.97 (0.95–1.00) ^j
Usual gait speed (+0.1 m/s)	0.80 (0.77–0.85)	0.84 (0.79–0.90) ^f	0.81 (0.74–0.88)	0.83 (0.74–0.92) ^j	0.80 (0.76–0.85)	0.85 (0.78–0.92) ^j
Chair stand time (+1 s)	1.09 (1.07–1.12)	1.06 (1.03–1.10) ^f	1.18 (1.10–1.27)	1.11 (1.03–1.21) ^j	1.09 (1.06–1.11)	1.06 (1.02–1.09) ^j
Muscle dysfunction (yes vs no) ^a	2.91 (2.02–4.19)	1.71 (1.16–2.52) ^f	2.60 (1.45–4.68)	1.68 (0.91–3.09) ^j	3.07 (1.92–4.92)	1.72 (1.04–2.85) ^j
Smoking (yes vs no)	0.98 (0.58–1.68)	1.39 (0.79–2.43) ^f	1.18 (0.62–2.26)	1.54 (0.79–3.01) ^j	0.95 (0.30–2.99)	1.09 (0.35–3.47) ^j
Alcohol consumption (yes vs no)	0.71 (0.50–0.99)	0.83 (0.58–1.21) ^f	0.78 (0.45–1.35)	0.93 (0.53–1.61) ^j	0.70 (0.42–1.16)	0.76 (0.46–1.27) ^j

^aMuscle dysfunction was defined as usual gait speed ≤0.8 m/s or grip strength <30 kg in men and <20 kg in women. ^bAdjusted for age, sex and body mass index (BMI). ^cAdjusted for region, sex and BMI. ^dAdjusted for region, age and sex. ^eAdjusted for region, age, sex and BMI. ^fAdjusted for age and BMI. ^gAdjusted for region and BMI. ^hAdjusted for region and age. ⁱAdjusted for region, age and BMI. ^jUrban region and men were used as references. CI, confidence interval; HR, hazard ratio.

determined its risk factors using Japanese population-based cohorts. Identified risk factors were region, age, underweight, obesity, handgrip strength, knee extension torque, usual gait speed, chair stand time and muscle dysfunction (determined by the EWGSOP algorithm for screening sarcopenia).

In the present study, we could not obtain information on causes of certified need of care in the LTCI system. Therefore, we could not analyze the direct association of each causing condition with such factors as anthropometric and physical performance measurements. The Government of Japan reported that the top five leading causes of certified need of care were cerebral stroke, dementia, asthenia as a result of older age, joint disease and fall-related fracture, comprising 71.6% of all causes in 2010.¹⁰ Based on these data, most of the causes of incident certification in the present study are inferred to be among the top five leading conditions.

Both low and high BMI were found to be risk factors for occurrence of certified need of care, showing an overall U-shaped association. This U-shaped association is similar to that between BMI and risk of death.^{11,12} The association between risk of death from cardiovascular disease and other causes, and BMI was reported to be U-shaped in East Asians,¹¹ whereas the risk of all-cause mortality versus BMI was also found to have a U-shaped association in Western European and North American populations.¹² High BMI is an established risk factor for chronic diseases, including hypertension, dyslipidemia and diabetes mellitus, which increase the risk of cerebral stroke.¹³ High BMI is also a major risk factor for knee osteoarthritis,^{14–17} which can cause ADL disability in the elderly.¹⁸ In contrast, low BMI is an established risk factor for osteoporosis and related fracture.¹⁹ It also might relate to asthenia, a condition of loss or lack of bodily strength as a result of chronic wasting disease. Underweight as a result of malnutrition or sarcopenia is suggested to be included in this category.

Other identified risk factors were handgrip strength, knee extension torque, usual gait speed, chair stand time and muscle dysfunction (determined by the EWGSOP algorithm for screening sarcopenia). Previous studies have reported that low muscle strength and physical performance were predictors of subsequent ADL disability in the elderly.^{20–23} The results of the present study are consistent with these previous reports. As many of the performance tests used in the present study are easy to carry out and evaluate, they can be utilized for screening elderly persons at high risk of certified need of care in the LTCI system. Those who were classified as having muscle dysfunction in the present study were at high risk of sarcopenia as well as certified need of care, regardless of muscle volume. Therefore, elderly persons screened by the EWGSOP algorithm are recommended to receive early interven-

tion programs for prevention of ADL disability and subsequent deterioration leading to certified need of care.

The Japanese Orthopedic Association proposed the concept of “locomotive syndrome” in 2007 for the promotion of preventive health care of locomotive organs.^{24–26} Locomotive syndrome refers to conditions under which the elderly have been receiving support or long-term care, or high-risk conditions under which they might soon require support or long-term care, that are caused by musculoskeletal disorders.^{24–26} Functional declines in locomotive organs, including muscle strength, walking speed and balancing ability, usually progress slowly and gradually. As such, it might be difficult for people to recognize this decline in their daily life. Therefore, it is of particular importance to raise awareness of the growing risk caused by these disorders, and to take action to improve and maintain the health of locomotive organs. Population approaches, including promotion of the concept of locomotive syndrome to both younger and older generations, are important, in addition to high-risk approaches, including identifying those at risk for certified need of care and practicing intervention programs to reduce the risk of certified need of care.

There were some limitations in the present study. As we could not obtain information on causing conditions, we could not determine the risk factors for occurrence of certified need of care with respect to each causing condition. Additional studies are necessary to identify those direct associations. In the present study, the rural region was at higher risk of incident certified need of care compared with the urban region. The reasons for this could include differences in available public and private transportation or delivery services regarding meals and commodities for the elderly. In addition to these, the threshold between certified and non-certified elderly might be different among municipalities, which could lead to regional differences. Although the Certification Committee for Long-term Care Need in each municipality determines certification in accordance with guidelines formulated by the Government, the Committee also has to consider assessment by the applicant's primary physician and objective evaluation results regarding physical and mental status, which could affect the threshold of certification. Another limitation was health bias. Participants at baseline in the present study were those who could walk to the survey site, and could understand and sign an informed consent form. As those who could not were not included in the analyses, the study participants do not truly represent the general population due to health bias. Therefore, incidence of certified need of care was most likely underestimated, which should be taken into consideration when generalizing the results of the present study.

In conclusion, the present study revealed the incidence of certified need of care in the national LTCI

system, and determined its risk factors using Japanese population-based cohorts. Both underweight and obesity were found to be risk factors for certified need of care, suggesting that maintenance of intermediate BMI is important for prevention. Low muscle strength and physical ability were also shown to be risk factors for certified need of care. Physical performance measures identified as predictors can be used as screening tools to identify high-risk individuals. Considering muscle dysfunction, screened by the EWGSOP algorithm, was a risk factor for occurrence, screened individuals are recommended to receive early intervention programs regardless of muscle volume. Further studies are necessary to develop intervention programs and to test their effectiveness, along with accumulation of epidemiological evidence, to prevent certified need of care and reduce the social and economic burdens associated with this condition.

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Disclosure statement

The authors declare no conflict of interest.

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Association of physical activities of daily living with the incidence of certified need of care in the long-term care insurance system of Japan: the ROAD study

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Abstract

Background The present study aimed to investigate association of physical activities of daily living with the incidence of certified need of care in the national long-term care insurance (LTCI) system in elderly Japanese population-based cohorts.

Methods Of the 3,040 participants in the baseline examination, we enrolled 1,773 (699 men, 1,074 women) aged 65 years or older who were not certified as in need of care-level elderly at baseline. Participants were followed during an average of 4.0 years for incident certification of need of care in the LTCI system. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) was used assess function. Associated factors in the baseline examination with the occurrence were determined by multivariate Cox proportional hazards regression analysis. Receiver operating characteristic curve analysis was performed to evaluate cut-off values for discriminating between the occurrence and the non-occurrence group.

Results All 17 items in the WOMAC function domain were significantly associated with the occurrence of certified need of care in the overall population. Cut-off values of the WOMAC function score that maximized the sum of sensitivity and specificity were around 4–6 in the overall population, in men, and in women. Multivariate Cox hazards regression analysis revealed that a WOMAC function score ≥ 4 was significantly associated with occurrence with the highest hazard ratio (HR) for occurrence after adjusting for confounders in the overall population (HR [95 % confidence interval (CI)] 2.54 [1.76–3.67]) and in women [HR (95 % CI) 3.13 (1.95–5.02)]. A WOMAC function score ≥ 5 was significantly associated with the highest HR for occurrence in men [HR (95 % CI) 1.88 (1.03–3.43)].

Conclusions Physical dysfunction in daily living is a predictor of the occurrence of certified need of care. Elderly men with a WOMAC function score ≥ 5 and women with a score ≥ 4 should undergo early intervention programs to prevent subsequent deterioration.

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Introduction

Japan is a super-aged society experiencing an unprecedented aging of the population. The proportion of the population aged 65 years or older was 23 % in 2010, and is expected to reach 30.1 % in 2024 and 39 % in 2051 [1]. This leads to an increasing proportion of disabled elderly requiring support or long-term care, imposing enormous economic and social burdens on the country. The Japanese Government started the national long-term care insurance (LTCI) system in 2000 based on the Long-Term Care Insurance Act [2]. The aim was to certify need of care-level elderly and to provide suitable care services according to the level of care required [7 levels, including requiring support (levels 1 and 2) and requiring long-term care (levels 1–5)]. The total number of certified need of care-level elderly was reported to be 5 million in 2011 [2]. Certification of need of care in the national LTCI system is an important outcome in Japan not only because of its massive social and economic burdens, but also because it is urgently necessary to reduce risk and decrease the number of disabled elderly requiring care in their activities of daily living (ADLs). It is critically important to accumulate epidemiologic evidence, including identification of predictors, to establish evidence-based prevention strategies. However, no studies have determined the association of physical ADLs with the incidence of certified need of care in the national LTCI system using large-scale, population-based cohorts. The objective of the present study was to investigate the association of physical ADLs with the incidence of certified need of care in the national LTCI system and determine its predictors in elderly participants of large-scale, population-based cohorts of the research on osteoarthritis/osteoporosis against disability (ROAD) study.

Subjects and methods

Participants

The analysis was based on data collected from cohorts established in 2005 for the ROAD study. Details of the cohorts have been reported elsewhere [3, 4]. Briefly, a baseline database was created from 2005 to 2007, which included clinical and genetic information on 3,040 residents of Japan (1,061 men, 1,979 women). Participants were recruited from resident registration listings in three communities, namely, an urban region in Itabashi, Tokyo, and rural regions in Hidakagawa and Taiji, Wakayama. Participants in the urban region in Itabashi were recruited from those of a cohort study [5] in which the participants were randomly drawn from the register database of Itabashi

ward residents, with a response rate in the age group >60 years of 75.6 %. Participants in the rural regions in Hidakagawa and Taiji were recruited from resident registration lists, with response rates in the groups aged >60 years of 68.4 and 29.3 %, respectively. Inclusion criteria were the ability to (1) walk to the survey site, (2) report data, and (3) understand and sign an informed consent form. For the present study, we enrolled 1,773 participants (699 men, 1,074 women; mean age 75.4 years) aged 65 years or older who were not certified as in need of care-level elderly in the national LTCI system at baseline. All participants provided written informed consent, and the study was conducted with approval from the ethics committees of the participating institutions.

Baseline procedures

Participants completed an interviewer-administered questionnaire containing 400 items that included lifestyle information, such as smoking habits, alcohol consumption, and physical activity. At baseline, anthropometric measurements, including height and weight, were taken, and body mass index (BMI) [weight (kg)/height² (m²)] was estimated based on the measured height and weight.

Assessment of physical ADLs

We used the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) for assessment of physical ADLs. The WOMAC is a health status instrument, consisting of three domains: pain, stiffness, and physical function. We used the WOMAC function domain to evaluate physical ADLs. It consisted of 17 items: assessing difficulties in descending stairs, ascending stairs, rising from sitting, standing, bending to floor, walking on a flat surface, getting in/out of car/bus, going shopping, putting on socks/stockings, rising from bed, taking off socks/stockings, lying in bed, getting into/out of bath, sitting, getting on/off toilet, heavy domestic duties, and light domestic duties. Each item in the domain is graded on either a 5-point Likert scale (scores of 0–4) or a 100-mm visual analog scale [6, 7]. In the present study, we used the Likert scale (version LK 3.0). Items were rated from 0 to 4; 0, no difficulty; 1, mild difficulty; 2, moderate difficulty; 3, severe difficulty; 4, extreme difficulty. The domain score ranges from 0 to 68. Japanese versions of the WOMAC have been validated [8].

Certification of need of care in the LTCI system

The nationally uniform criteria for long-term care need certification was established objectively by the Japanese Government, and certification of need of care-level elderly

is determined based on evaluation results by the Certification Committee for Long-term Care Need in municipalities in accordance with basic guidelines formulated by the Government. The process of eligibility for certification of need of care in the LTCI system was described in detail by Chen et al. [9]. An elderly person who requires help with ADLs or the caregiver contacts the municipal government to request official certification of care needs. After the application, a trained official visits the home to assess the current physical status of the elderly person, including presence or absence of muscle weakness or joint contracture of limbs, and difficulties in sitting-up, standing-up, maintaining sitting or standing position, transferring from one place to another, standing on one leg, walking, bathing, dressing, and other ADLs. Mental status, including dementia, also is assessed. These data are analyzed to calculate a standardized score for determination of the level of care needs (certified support, levels 1–2; or long-term care, levels 1–5). In addition, the primary physician of the applicant assesses physical and mental status, including information on diseases causing ADL disability and the extent of disabilities caused by them. Finally, the Certification Committee for Long-term Care Need reviews the data and determines the certification and its level.

Follow-up and definition of incident certified need of care

After the baseline ROAD survey, participants who were not certified as in need of care-level elderly at baseline were followed for incident certification of need of care in the LTCI system. Incident certified need of care was defined as the incident certified 7 levels, including requiring support (levels 1–2) and requiring long-term care (levels 1–5). Information on the presence or absence of certification of need of care and its date of occurrence were collected by the resident registration listings in three communities every year up to 2010, and were used for analyses in the present study.

Statistical analysis

All statistical analyses were performed using STATA statistical software (STATA, College Station, TX, USA). Differences in values of the parameters between the two groups were tested for significance using the unpaired Student’s *t* test, the Mann–Whitney’s *U* test, and Chi-square test. We used receiver operating characteristic (ROC) curve analysis to determine a cut-off value of the WOMAC function score for discriminating two distinct groups: an occurrence and a non-occurrence group of certified need of care. Cut-off values were determined that maximized the sum of sensitivity and specificity. Factors

associated with the occurrence of certified need of care were determined using Cox proportional hazards regression analysis; hazard ratios (HRs) and 95 % confidence intervals (CIs) were determined after adjusting for region, age, sex, and BMI. Smoking habit and alcohol consumption were not included as confounders because they were not significantly associated with the incidence of certified need of care.

Results

Of the 1,773 participants who were not certified as in need of care-level elderly at baseline, information on

Table 1 Baseline characteristics of population at risk for the certified need of care in the LTCI system

	Men	Women
No. of subjects	699	1,074
Age (years)	75.6 (5.1)	75.2 (5.3)
Height (cm)	160.9 (6.0)	147.9 (6.0) ^b
Weight (kg)	59.4 (9.1)	50.0 (8.3) ^b
BMI (kg/m ²)	22.9 (2.9)	22.8 (3.4)
Smoking (%)	21.0	3.2 ^c
Alcohol consumption, %	61.2	23.0 ^c
WOMAC function domain		
Descending stairs, pts ^a	0 (0, 0, 1, 1)	0 (0, 0, 1, 2) ^d
Ascending stairs, pts ^a	0 (0, 0, 1, 1)	0 (0, 0, 1, 2)
Rising from sitting, pts ^a	0 (0, 0, 0, 1)	0 (0, 0, 1, 1) ^d
Standing, pts ^a	0 (0, 0, 0, 1)	0 (0, 0, 1, 1) ^d
Bending to floor, pts ^a	0 (0, 0, 0, 1)	0 (0, 0, 1, 1)
Walking on a flat surface, pts ^a	0 (0, 0, 0, 1)	0 (0, 0, 0, 1)
Getting in/out of car/bus, pts ^a	0 (0, 0, 0, 1)	0 (0, 0, 1, 1) ^d
Going shopping, pts ^a	0 (0, 0, 0, 1)	0 (0, 0, 0, 1) ^d
Putting on socks/stockings, pts ^a	0 (0, 0, 0, 1)	0 (0, 0, 0, 1) ^d
Rising from bed, pts ^a	0 (0, 0, 0, 1)	0 (0, 0, 0, 1) ^d
Taking off socks/stockings, pts ^a	0 (0, 0, 0, 1)	0 (0, 0, 0, 1) ^d
Lying in bed, pts ^a	0 (0, 0, 0, 0)	0 (0, 0, 0, 1) ^d
Getting into/out of bath, pts ^a	0 (0, 0, 0, 0)	0 (0, 0, 0, 1) ^d
Sitting, pts ^a	0 (0, 0, 0, 0)	0 (0, 0, 0, 0) ^d
Getting on/off toilet, pts ^a	0 (0, 0, 0, 1)	0 (0, 0, 1, 2) ^d
Heavy domestic duties, pts ^a	0 (0, 0, 0, 1)	0 (0, 0, 0, 1) ^d
Light domestic duties, pts ^a	0 (0, 0, 0, 1)	0 (0, 0, 0, 1) ^d
Total, pts ^a	1 (0, 0, 5, 12)	2 (0, 0, 8, 17) ^d

Except where indicated otherwise, values are mean (SD)

LTCI long-term care insurance system, BMI body mass index, WOMAC the Western Ontario and McMaster Universities Arthritis Index

^a Median (10, 25, 75, and 90 percentile)

^b *P* < 0.05 vs men by unpaired Student’s *t* test

^c *P* < 0.05 vs men by Chi-square test

^d *P* < 0.05 vs men by Mann–Whitney *U* test

Table 2 Association of physical activities of daily living with the occurrence of certified need of care in the LTCI system

Physical activity	Overall population		Men		Women	
	HR (95 % CI)	<i>P</i> value	HR (95 % CI)	<i>P</i> value	HR (95 % CI)	<i>P</i> value
Descending stairs, pts	1.47 (1.26, 1.72)	<0.001	1.29 (0.96, 1.74)	0.089	1.56 (1.30, 1.87)	<0.001
Ascending stairs, pts	1.47 (1.25, 1.73)	<0.001	1.29 (0.93, 1.77)	0.123	1.55 (1.29, 1.86)	<0.001
Rising from sitting, pts	1.58 (1.34, 1.88)	<0.001	1.38 (0.95, 1.99)	0.092	1.67 (1.37, 2.03)	<0.001
Standing, pts	1.64 (1.41, 1.91)	<0.001	1.39 (1.02, 1.90)	0.037	1.73 (1.45, 2.06)	<0.001
Bending to floor, pts	1.57 (1.32, 1.85)	<0.001	1.61 (1.15, 2.27)	0.006	1.57 (1.29, 1.90)	<0.001
Walking on a flat surface, pts	1.57 (1.30, 1.90)	<0.001	1.25 (0.88, 1.77)	0.22	1.78 (1.41, 2.23)	<0.001
Getting in/out of car/bus, pts	1.76 (1.47, 2.10)	<0.001	1.60 (1.14, 2.26)	0.007	1.85 (1.50, 2.29)	<0.001
Going shopping, pts	1.72 (1.46, 2.03)	<0.001	1.55 (1.14, 2.11)	0.005	1.81 (1.48, 2.21)	<0.001
Putting on socks/stockings, pts	1.60 (1.33, 1.92)	<0.001	1.41 (0.98, 2.03)	0.065	1.71 (1.37, 2.12)	<0.001
Rising from bed, pts	1.68 (1.40, 2.03)	<0.001	1.41 (0.98, 2.02)	0.066	1.83 (1.47, 2.29)	<0.001
Taking off socks/stockings, pts	1.64 (1.37, 1.98)	<0.001	1.48 (1.01, 2.16)	0.046	1.72 (1.39, 2.13)	<0.001
Lying in bed, pts	1.82 (1.44, 2.30)	<0.001	1.96 (1.13, 3.40)	0.017	1.79 (1.38, 2.32)	<0.001
Getting into/out of bath, pts	1.71 (1.43, 2.04)	<0.001	1.64 (1.15, 2.33)	0.006	1.75 (1.43, 2.15)	<0.001
Sitting, pts	2.21 (1.73, 2.82)	<0.001	1.92 (1.14, 3.22)	0.014	2.32 (1.75, 3.06)	<0.001
Getting on/off toilet, pts	1.87 (1.52, 2.29)	<0.001	1.51 (1.00, 2.27)	0.05	2.09 (1.63, 2.68)	<0.001
Heavy domestic duties, pts	1.27 (1.09, 1.49)	0.003	1.20 (0.89, 1.62)	0.238	1.33 (1.10, 1.60)	0.003
Light domestic duties, pts	1.68 (1.41, 2.01)	<0.001	1.49 (1.07, 2.07)	0.019	1.80 (1.45, 2.24)	<0.001

Hazard ratios (HRs) and 95 % confidence intervals (CIs) were determined by Cox proportional hazards regression analysis after adjusting for age, sex, body mass index, and region in the overall population, and after adjusting for age, body mass index, and region in men and in women, respectively

LTCI long-term care insurance system

certification of need of care could be obtained in 1,760 (99.3 %) during the average 4.0-year follow-up. Fifty-four men and 115 women were certified as in need of care-level elderly in the national LTCI system, whereas, 1,591 remained uncertified during the follow-up period. The average period for the certification was 2.3 years. Among the above 54 men and 115 women, those who were certified as requiring long-term care level 1, 2, 3, 4, and 5 were 7, 9, 2, 4, 3 men, and 12, 17, 9, 4, 4 women, respectively. One hundred and twenty-six participants died and eight moved away. Incidence of certified need of care in the LTCI system was 2.3/100 person-years in the overall population, and 2.0/100 person-years in men and 2.5/100 person-years in women. Table 1 shows the baseline characteristics of the population at risk for occurrence of certified need of care in the LTCI system. The score of each item in the WOMAC function domain was significantly higher in women than in men in almost all items.

We then investigated association of each item in the WOMAC function domain with the occurrence of certified need of care in the LTCI system (Table 2). All 17 items in the WOMAC function domain were significantly associated with the occurrence of the certified need of care in the overall population and in women. In men, standing, bending to floor, getting in/out of car/bus, going shopping,

taking off socks/stockings, lying in bed, getting into/out of bath, sitting, and light domestic duties were significantly associated with the occurrence of certified need of care, whereas other ADLs were not. In addition, the value of HR for each item in the association was higher in women than in men in 15 of 17 items.

Next we determined cut-off values of total score of the WOMAC function domain for discriminating two groups: an occurrence and a non-occurrence group of certified need of care using ROC curve analysis. The area under ROC curve was 0.70 in the overall population, 0.61 in men, and 0.74 in women (Fig. 1). The cut-off value of the WOMAC function score that maximized the sum of sensitivity and specificity was 6, 5, and 6 in the overall population, in men, and in women, respectively. In addition, the sensitivity/specificity was 57.3/75.0 % in the overall population, 45.7/75.0 % in men, and 64.4/72.6 % in women, respectively (Table 3). Furthermore, the cut-off value by which the sum was the second largest was 4 in the overall population, 4 in men, and 4 in women, and the sensitivity/specificity was 65.3/66.7 % in the overall population, 50.0/70.0 % in men, and 72.1/64.5 % in women, respectively (Table 3).

Because ROC curve analysis is a univariate analysis, we performed multivariate Cox hazards regression analysis to determine the cut-off value of the WOMAC function score for best discriminating between an occurrence and a non-

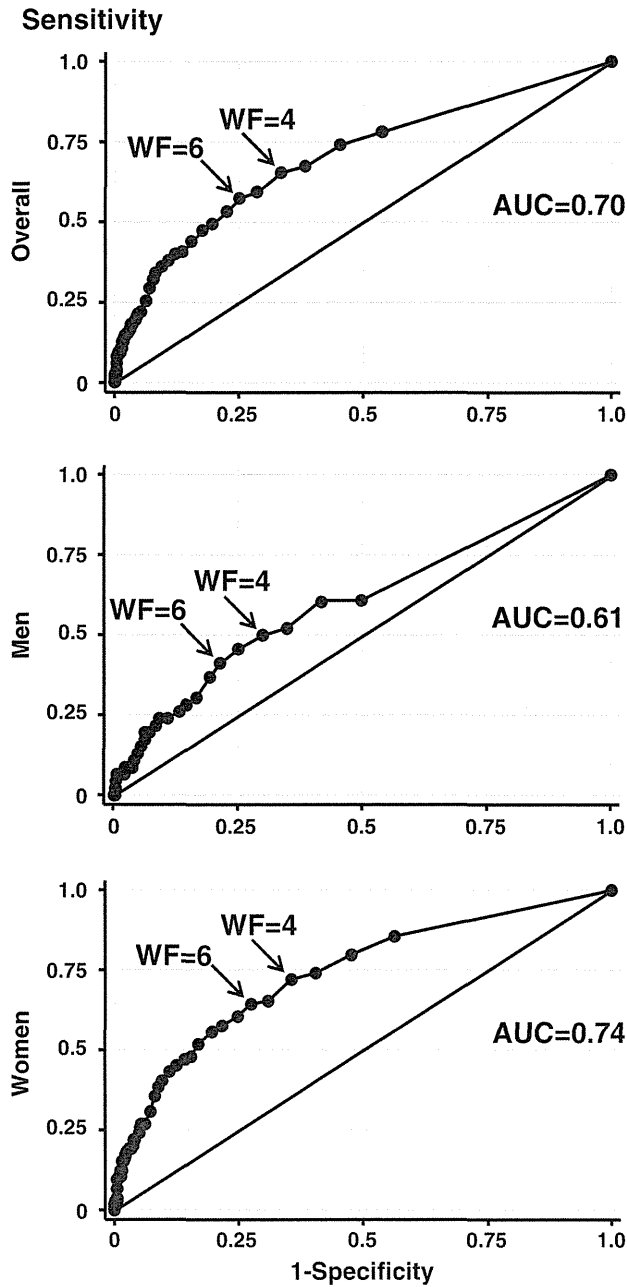


Fig. 1 Receiver operating characteristic (ROC) curve analysis for discriminating the occurrence group of certified need of care in the overall population, in men, and in women. *AUC* area under ROC curve, *WF* WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) function score

occurrence group of certified need of care after adjusting for age, sex, BMI, and region (Table 4). The group with WOMAC function score ≥ 4 was significantly associated with the occurrence of certified need of care compared with the group with the score < 4 with the highest HR in the overall population [HR 2.54, 95 % CI (1.76–3.67)] and in women [HR 3.13, 95 % CI (1.95–5.02)]. In men, the group with WOMAC function score ≥ 5 was significantly

Table 3 Sensitivity and specificity of the occurrence of certified need of care determined by the cut-off point of the WOMAC function score

Cut-off point	Overall population			Men			Women		
	Sensitivity (%)	Specificity (%)	Sensitivity + specificity (%)	Sensitivity (%)	Specificity (%)	Sensitivity + specificity (%)	Sensitivity (%)	Specificity (%)	Sensitivity + specificity (%)
WF = 4pts	65.3	66.7	132.0	50.0	70.0	120.0	72.1	64.5	136.6
WF = 5pts	59.3	71.4	130.7	45.7	75.0	120.7	65.4	69.2	134.6
WF = 6pts	57.3	75.0	132.3	41.3	78.6	119.9	64.4	72.6	137.0

WOMAC the Western Ontario and McMaster Universities Arthritis Index, *WF* WOMAC function score

Table 4 Association of groups divided by the WOMAC function score with the occurrence of certified need of care in the LTCI system

	Overall population		Men		Women	
	HR (95 % CI)	<i>P</i> value	HR (95 % CI)	<i>P</i> value	HR (95 % CI)	<i>P</i> value
WF \geq 4 pts vs WF < 4 pts	2.54 (1.76, 3.67)	<0.001	1.85 (1.01, 3.39)	0.045	3.13 (1.95, 5.02)	<0.001
WF \geq 5 pts vs WF < 5 pts	2.35 (1.64, 3.36)	<0.001	1.88 (1.03, 3.43)	0.040	2.71 (1.73, 4.27)	<0.001
WF \geq 6 pts vs WF < 6 pts	2.50 (1.75, 3.58)	<0.001	1.84 (1.00, 3.39)	0.051	3.03 (1.93, 4.76)	<0.001

Hazard ratios (HRs) and 95 % confidence intervals (CIs) were determined by Cox proportional hazards regression analysis after adjusting for age, sex, body mass index, and region in the overall population, and after adjusting for age, body mass index, and region in men and in women, respectively

WOMAC the Western Ontario and McMaster Universities Arthritis Index, LTCI long-term care insurance system, WF WOMAC function score

Table 5 Association of the WOMAC function score with the occurrence of different certified need of care levels in the LTCI system

Outcome variable	Overall population		Men		Women	
	HR (95 % CI)	<i>P</i> value	HR (95 % CI)	<i>P</i> value	HR (95 % CI)	<i>P</i> value
RSL1–2 and RCL 1–5	1.05 (1.03, 1.06)	<0.001	1.03 (1.01, 1.06)	0.008	1.05 (1.04, 1.07)	<0.001
RCL 1–5	1.05 (1.03, 1.07)	<0.001	1.04 (1.00, 1.07)	0.046	1.06 (1.03, 1.08)	<0.001
RCL 2–5	1.06 (1.04, 1.08)	<0.001	1.04 (1.01, 1.08)	0.015	1.06 (1.04, 1.09)	<0.001
RCL 3–5	1.05 (1.03, 1.08)	<0.001	1.05 (0.99, 1.10)	0.099	1.06 (1.02, 1.09)	0.001
RCL 4–5	1.04 (1.00, 1.08)	0.048	1.02 (0.95, 1.10)	0.501	1.05 (1.00, 1.10)	0.057
RCL 5	1.01 (0.93, 1.09)	0.830	0.99 (0.82, 1.20)	0.945	1.01 (0.93, 1.11)	0.780

Hazard ratios (HRs) and 95 % confidence intervals (CIs) were determined by Cox proportional hazards regression analysis after adjusting for age, sex, body mass index, and region in the overall population, and after adjusting for age, body mass index, and region in men and in women, respectively

WOMAC the Western Ontario and McMaster Universities Arthritis Index, LTCI long-term care insurance system, RSL requiring support level, RCL requiring long-term care level

associated with the occurrence of certified need of care compared with the group with a score of <5 with the highest HR [HR 1.88, 95 % CI (1.03–3.43)].

Furthermore, we examined association of the WOMAC function domain with the occurrence of different certified need of care levels in the LTCI system (Table 5). When the outcome variable of the occurrence was defined as requiring support level (RSL) 1–2 and requiring long-term care level (RCL) 1–5, RCL 1–5, and RCL 2–5, there were significant associations in the overall population, in men, and in women, respectively. When the outcome variable of the occurrence was defined as RCL 3–5, there were significant associations in the overall population and in women. When the outcome variable of the occurrence was defined as RCL 4–5, there was significant association in the overall population.

Discussion

The present study determined association of physical ADLs with the incidence of certified need of care in the national LTCI system in elderly participants of Japanese population-based cohorts. All 17 items in the WOMAC function

domain were significantly associated with the occurrence of certified need of care in the overall population. ROC curve analysis showed that cut-off values of the WOMAC function score of around 4–6 maximized the sum of sensitivity and specificity of the occurrence of certified need of care. Furthermore, multivariate Cox hazards regression analysis revealed that the group with WOMAC function score \geq 4 was significantly associated with the occurrence of certified need of care with the highest HR after adjusting for confounders in the overall population and in women, while the group with WOMAC function score \geq 5 was significantly associated with the highest HR in men.

In the present study, we could not obtain information on causes of certified need of care in the LTCI system. Therefore, we could not analyze the direct association of each causing condition with the WOMAC function domain. The Government of Japan reported that the top five leading causes of certified need of care were cerebral stroke (21.5 %), dementia (15.3 %), asthenia as a result of older age (13.7 %), joint disease (10.9 %) and fall-related fracture (10.2 %), comprising 71.6 % of all causes in 2010 [10]. Based on these data, most of the causes of incident certification in the present study are inferred to be among the top five leading conditions. Although we could not

know the exact percentage of each causing condition, joint disease and fall-related fracture are inferred to represent approximately 20 % in total causes of incident certification in the present study, and cerebral stroke, dementia, and asthenia as a result of older age are inferred to represent approximately 50 % in total causes of incident certification.

The Government of Japan also reported that the percentage of joint disease and fall-related fracture was 16.7 % for the cause of RCL 1–5 [10]. Furthermore, it was 17.6, 19.8, 14.8, 17.4, and 9.8 % for the cause of RCL 1, 2, 3, 4, and 5, respectively [10]. Although we could not know the exact percentage of joint disease and fall-related fracture for the cause of each RCL in the present study, the percentage for the cause of RCL 1–4 is inferred to be approximately 15 % or more based on the data of the Government of Japan, which may be the reason why the WOMAC domain was significantly associated with the occurrence of certified need of care including RCLs 1–4 in the overall population.

The WOMAC physical function domain assesses difficulties in ADLs, including going up/down stairs, getting in/out of a car and bath, shopping, and household duties. Therefore, results of the present study indicate that the severity of physical dysfunction in ADLs predicts subsequent deterioration in ADLs, leading to the occurrence of certified need of care. Previous studies reported that low physical function was a predictor of subsequent ADL disability in the elderly [11, 12]. Although no previous studies have investigated the association of physical ADLs with the incidence of certified need of care in the national LTCI system in large-scale population-based cohorts, those previous findings are consistent with the present results in that low physical activity predicted subsequent deterioration in ADLs.

All 17 items in the WOMAC domain were significantly associated with the occurrence of certified need of care in women. On the other hand, 9 of 17 items were significantly associated with the occurrence of certified need of care in men. In addition, the HR for each item in the association was higher in women than in men for 15 of 17 items. The sex difference identified in this association may be due to the difference in the prevalence of knee osteoarthritis between the sexes. Muraki et al. [13] reported that prevalence of radiographic knee osteoarthritis determined by the Kellgren–Lawrence grade ≥ 2 was 47.0 % in men and 70.2 % in women, respectively, in subjects aged 60 years and older in Japanese population-based cohorts. Therefore, women are more likely than men to be affected by knee osteoarthritis and have difficulties in physical function of the lower extremities, leading to higher scores on the WOMAC function scale. Another reason for the sex differences may be the weaker muscle strength in women; muscle strength in men is higher than that in women in all decades of life [14], which may obscure the association in

men, as muscle strength has been reported to be inversely associated with the WOMAC domains [15].

Functional declines in locomotive organs including physical ADLs usually progress slowly and gradually. As such, it may be difficult for people to recognize this decline in their daily life. Therefore, it is of particular importance to raise awareness of the growing risk caused by such disorders, and to take action to improve and maintain the health of the locomotive organs. The Japanese Orthopaedic Association proposed the concept of “locomotive syndrome” in 2007 for the promotion of preventive healthcare of the locomotive organs [16–18]. Locomotive syndrome refers to conditions under which the elderly have been receiving support or long-term care, or high-risk conditions under which they may soon require support or long-term care, that are caused by musculoskeletal disorders [16–18]. Population approaches, including promotion of the concept of locomotive syndrome to both younger and older generations, are important, in addition to high-risk approaches, including identifying those at risk for certified need of care and practicing intervention programs to reduce the risk of certified need of care.

Because the WOMAC function scale is a self-assessment questionnaire that is easy to conduct and evaluate, it can be used to screen elderly persons at high risk of certified need of care in the LTCI system. Multivariate Cox hazards regression analysis showed that a WOMAC function score of 5 in men and 4 in women best discriminated between the occurrence and the non-occurrence group of certified need of care in this study population. Elderly men with a WOMAC function score ≥ 5 had a 1.88-fold higher risk of occurrence of certified need of care compared with elderly men with a score < 5 . Elderly women with a WOMAC function score ≥ 4 had a 3.13-fold higher risk of occurrence of certified need of care compared with elderly women with a score < 4 . Elderly persons screened by these cut-off values should receive early intervention for the prevention of subsequent deterioration in ADLs that could lead to certified need of care. Further studies, along with the accumulation of epidemiologic evidence, are necessary to develop intervention programs that are safe and effective for elderly subjects who are at high risk of certified need of care.

There are some limitations in the present study. First, we could not obtain information on causes of certified need of care in the LTCI system. Therefore, we could not analyze the direct association of each causing condition with measured factors, and could not determine the risk factors for occurrence of certified need of care with respect to each causing condition. The Japanese government reported that the top five leading causes of certified need of care were cerebral stroke, dementia, asthenia, osteoarthritis, and fall-related fracture, comprising 71.6 % of all causes in 2010 [10]. Based on these data, most of the causes of incident certification in the present

study are inferred to be among the top five leading conditions. Additional studies are necessary to identify those direct associations. Second, participants at baseline in the present study were those who could walk to the survey site and could understand and sign an informed consent form. Since those who could not were not included in the analyses, the study participants do not truly represent the general population due to health bias, which should be taken into consideration when generalizing the results of the present study.

In conclusion, the present study determined association of physical ADLs with the occurrence of certified need of care in the LTCI system in elderly participants of Japanese population-based cohorts. The severity of physical dysfunction is a predictor of the occurrence of certified need of care. Further studies are necessary to develop intervention programs that are safe and effective for elderly individuals who are at high risk of certified need of care.

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Conflict of interest There are no conflicts of interest.

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