TABLE 1. Comparison of Baseline Characteristics of Follow-up Group and Non–Follow-up Group

Factors	Non–Follow-up (%)	Follow-up (%)	P*
Age (yr)			
<40	1631 (58.5)	1205 (37.7)	<0.001
40–49	660 (23.7)	993 (31.1)	
≥50	499 (17.9)	996 (31.2)	
Sex			
Male	2417 (82.4)	2577 (80.7)	0.092
Female	517 (17.6)	616 (19.3)	
Obesity			
<BMI 25 kg/m^2	2117 (73.7)	2422 (76.4)	0.013
≥BMI 25 kg/m^2 (obese)	757 (26.3)	747 (23.6)	
Manual handling at work			
No manual handling	1823 (65.3)	2231 (72.6)	<0.001
Manual handling of <20 kg	389 (13.9)	303 (9.9)	
Manual handling of ≥20 kg	578 (20.7)	541 (17.6)	

Totals may not sum to 100% because of rounding.
**Pearson χ^2.*
BMI indicates body mass index.

less than 20 kg, 80 (11.0%) manually handled objects 20 kg or more, or worked as a caregiver.

Incidence of New-Onset Sciatica

Of a total of 765 eligible participants, 141 (18.4%) reported a new episode of sciatica during the 2-year follow-up period (18 missing cases).

Association Between New-Onset Sciatica and Potential Risk Factors

Crude and adjusted ORs for new-onset sciatica and their 95% confidence intervals are shown in Table 2. In crude analyses, age and obesity were significantly associated with new-onset sciatica (ORs of 1.50–1.84) ($P < 0.1$). Similarly, in adjusted analyses, obesity and mental workload in a qualitative aspect were significantly associated with new-onset sciatica after adjusting for age and sex (ORs of 1.39–1.80) ($P < 0.1$). Finally, all of these factors were simultaneously included in the same model to control for the other factors, as well as age and sex. As shown in Table 3, age (≥50 *vs.* <40) and obesity remained statistically significant in the multivariate analysis ($P < 0.05$). The ORs for age and obesity remained similar in both the multivariate analysis and the crude and/or adjusted analyses. A univariate logistic regression analysis was also performed in each age and sex strata to examine whether their effects on obesity and mental workload in a qualitative aspect in relation to new-onset sciatica ($P < 0.05$). As shown in Table 4, obesity in age (≥50) and male sex, and mental workload in age (<40) were statistically significant.

DISCUSSION

It is established that individual and work-related factors predispose the development of new-onset sciatica. However, information on the influence of psychosocial factors is conflicting. In our earlier study using data from the Japan epidemiological research of Occupation-related Back pain study, ergonomic factors (*i.e.*, frequent lifting) and work-related psychosocial factors (*i.e.*, interpersonal stress at workplace, monotonous tasks) were identified as potential risk factors for new-onset of nonspecific LBP with disability in workers who had no LBP during the year before the baseline survey.[30] Conversely, in this study, individual factors were the only identified potential risk factors in workers who reported no history of sciatica as well as no LBP in the year before baseline. Both studies were conducted among asymptomatic workers at baseline, yet the results varied depending upon the presence of pathology.

In this study, age was associated with the risk of developing new-onset sciatica, which is consistent with earlier research.[9] Although age is often used as a control variable in exploratory studies, not as an independent variable, it is appropriate to include age as an independent risk factor when exploring new-onset sciatica. The risk of sciatic pain seems to increase with age as the intervertebral discs and the spinal canal can often degenerate because of morphologic and functional alternations.[9] As a result, posterior disc bulges cause sciatic pain.[31]

Obesity was also found to be a risk factor for new-onset sciatica, which is again consistent with the findings of a previous report.[7] Obesity may increase the mechanical load on the intervertebral discs, but recent research has revealed that obesity may also be associated with neuropathic disorders. It has been found that obesity alters production of adipokines, including leptin and resistin, and locally produced proinflammatory cytokines such as TNF-α and IL-6 induced by obesity leads to a subclinical inflammatory condition of the white adipose tissue (WAT).[32,33] Similarly, animal work has shown that the adipokine, produced mainly by adipocytes, plays an important role not only in metabolic regulation and obesity, but also in the development of neuropathic disorder.[34–36] In addition, Miscio *et al*[37] suggested that peripheral nerve conduction abnormalities, in the lower extremities of nondiabetic obese patients with subclinical peripheral nerve impairment, increased risk for peripheral neuropathy. Thus, it seems reasonable that metabolic dysfunction may hypothetically mediate neuropathic pain including sciatica in humans. Given these earlier findings, obesity may create an environment that could easily trigger new-onset sciatica.

Results of this study implicate that reduction or prevention of obesity may offer important protection against the development of sciatica. The management of overweight and obesity by exercising, weight control, and improving dietary

TABLE 2. Crude and Adjusted Odds Ratios of Baseline Factors for Cases of New-Onset Sciatica

Factors	%	Crude OR	95% CI	*P*	Adjusted OR	95% CI	*P*
Age (yr)							
<40	37.6	1.00					
40–49	29.6	1.50	0.94–2.37	0.087			
≥50	32.8	1.57	1.00–2.46	0.048			
Sex							
Male	88.5	1.00					
Female	11.5	0.90	0.50–1.62	0.718			
Obesity							
<BMI 25 kg/m^2	77.9	1.00			1.00		
≥BMI 25 kg/m^2 (obese)	22.1	1.84	1.23–2.78	0.003	1.80	1.19–2.72	0.005
Height							
<167 cm (female)/<180 cm (male)	94.0	1.00			1.00		
≥167 cm (female)/≥180 cm (male)	6.1	0.78	0.34–1.79	0.564	0.87	0.37–2.00	0.736
Smoking habits							
Nonheavy smoker	71.5	1.00			1.00		
Heavy smoker	28.5	1.35	0.89–2.03	0.157	1.20	0.76–1.88	0.432
Education							
College/university	71.8	1.00			1.00		
High school/junior high school	28.2	0.94	0.62–1.42	0.765	0.85	0.56–1.31	0.468
Hours of sleep							
< 5 hr	3.9	1.00			1.00		
≥ 5 hr	96.1	1.67	0.72–3.85	0.229	1.93	0.82–4.51	0.131
Exercise habits							
≥Once per week	36.6	1.00			1.00		
<Once per week	63.4	0.97	0.66–1.42	0.866	1.03	0.69–1.52	0.899
Flexibility							
Flexible	76.6	1.00			1.00		
Not flexible	23.4	1.05	0.67–1.64	0.846	1.00	0.64–1.58	0.986
Experience in current job							
<5 yr	31.4	1.00			1.00		
≥5 yr	68.6	0.74	0.50–1.08	0.121	0.72	0.49–1.07	0.102
Working hours per week							
<60 hr	85.9	1.00			1.00		
≥60 hr	14.1	0.87	0.51–1.50	0.620	0.94	0.54–1.64	0.829
Work shift							
Regular shift	86.4	1.00			1.00		
Irregular shift	13.6	1.22	0.73–2.04	0.449	1.30	0.77–2.19	0.328

(Continued)

TABLE 2. (*Continued*)

Factors	%	Crude OR	95% CI	*P*	Adjusted OR	95% CI	*P*
Employment status							
Full-time	95.9	1.00			1.00		
Others	4.1	1.06	0.43–2.65	0.896	0.98	0.38–2.51	0.958
Manual handling at work							
No manual handling (desk work)	78.4	1.00			1.00		
Manual handling of objects <20 kg	10.6	1.40	0.79–2.47	0.250	1.47	0.83–2.63	0.188
Manual handling of objects ≥20-kg objects or working as a caregiver	11.0	1.24	0.69–2.20	0.473	1.34	0.73–2.46	0.351
Bending							
Not frequent	95.0	1.00			1.00		
Frequent	5.0	1.19	0.53–2.66	0.674	1.22	0.54–2.75	0.639
Twisting							
Not frequent	97.0	1.00			1.00		
Frequent	3.0	0.42	0.10–1.81	0.244	0.41	0.09–1.79	0.235
Lifting							
Not frequent	95.7	1.00			1.00		
Frequent	4.3	0.98	0.40–2.44	0.973	1.02	0.41–2.57	0.960
Pushing							
Not frequent	97.7	1.00			1.00		
Frequent	2.3	1.32	0.42–4.12	0.629	1.34	0.43–4.22	0.616
Hours of driving per day							
<4 hr	92.5	1.00			1.00		
≥4 hr	7.5	1.25	0.64–2.45	0.514	1.30	0.66–2.56	0.456
Hours of desk work							
<6 hr per day	45.7	1.00			1.00		
≥6 hr per day	54.3	1.03	0.72–1.50	0.856	1.03	0.71–1.50	0.866
Mental workload (quantitative aspect)							
Not stressed	59.1	1.00			1.00		
Stressed	40.9	0.88	0.60–1.28	0.488	0.91	0.62–1.34	0.642
Mental workload (qualitative aspect)							
Not stressed	60.0	1.00			1.00		
Stressed	40.1	1.36	0.94–1.97	0.104	1.39	0.96–2.02	0.085
Physical workload							
Not stressed	70.7	1.00			1.00		
Stressed	29.3	1.13	0.76–1.69	0.539	1.21	0.80–1.81	0.364
Interpersonal stress at work							
Not stressed	84.2	1.00			1.00		
Stressed	15.8	1.20	0.74–1.95	0.466	1.31	0.80–2.15	0.285

(*Continued*)

TABLE 2. (*Continued*)

Factors	%	Crude OR	95% CI	*P*	Adjusted OR	95% CI	*P*
Work environmental stress							
Not stressed	78.3	1.00			1.00		
Stressed	21.7	1.18	0.77–1.82	0.449	1.28	0.82–1.99	0.276
Job control							
Controlled	31.2	1.00			1.00		
Not controlled	68.8	1.03	0.70–1.51	0.875	1.04	0.71–1.52	0.856
Utilization of skills and expertise							
Utilization of skills and expertise	83.4	1.00			1.00		
No utilization of skills and expertise	16.6	0.97	0.59–1.59	0.906	0.96	0.58–1.59	0.882
Job fitness							
Feeling fit	79.5	1.00			1.00		
Not feeling fit	20.5	1.36	0.88–2.09	0.163	1.37	0.89–2.11	0.154
Reward to work							
Satisfied	80.4	1.00			1.00		
Not satisfied	19.6	1.13	0.72–1.78	0.583	1.14	0.72–1.79	0.578
Vigor							
Vigorous	89.1	1.00			1.00		
Not vigorous	10.9	1.25	0.72–2.19	0.427	1.26	0.72–2.21	0.425
Anger							
Not angry	76.5	1.00			1.00		
Angry	23.5	1.22	0.80–1.86	0.358	1.30	0.84–1.20	0.233
Fatigue							
No fatigue	77.7	1.00			1.00		
Fatigue	22.3	0.93	0.60–1.45	0.750	0.98	0.62–1.55	0.944
Anxiety							
Not anxious	82.8	1.00			1.00		
Anxious	17.2	1.40	0.88–2.21	0.154	1.45	0.91–2.31	0.113
Depressed mood							
Not feeling depressed	76.9	1.00			1.00		
Depressed	23.1	1.26	0.83–1.93	0.278	1.28	0.84–1.97	0.252
Somatic symptoms							
No somatic symptoms	87.8	1.00			1.00		
Somatic symptoms	12.2	1.47	0.87–2.47	0.148	1.48	0.87–2.49	0.145
Support by supervisors							
Supported	78.5	1.00			1.00		
Not supported	21.5	1.12	0.72–1.73	0.627	1.13	0.73–1.76	0.591
Support by coworkers							
Supported	66.7	1.00			1.00		
Not supported	33.3	0.95	0.64–1.41	0.800	0.93	0.63–1.38	0.719

(*Continued*)

TABLE 2. (*Continued*)

Factors	%	Crude OR	95% CI	*P*	Adjusted OR	95% CI	*P*
Support by family or friends							
Supported	83.6	1.00			1.00		
Not supported	16.4	1.01	0.62–1.66	0.964	1.04	0.63–1.73	0.868
Daily-life satisfaction							
Satisfied	76.4	1.00			1.00		
Not satisfied	23.7	1.04	0.68–1.61	0.844	1.10	0.71–1.70	0.664
Monotonous work							
Not monotonous	84.4	1.00			1.00		
Monotonous	15.6	0.70	0.40–1.21	0.203	0.72	0.41–1.25	0.239
Family history of LBP with disability							
No LBP with disability	86.4	1.00			1.00		
LBP with disability	13.6	1.23	0.73–2.05	0.433	1.27	0.75–2.14	0.368

Data adjusted for age and sex.
Totals may not sum to 100% because of rounding.
BMI indicates body mass index; CI, confidence interval; LBP, low back pain; OR, odds ratio.

intake is encouraged. Despite the small proportion of workers experiencing sciatica during the follow-up period (approximately 18%), economic loss at workplaces because of sciatica cannot be overestimated. Promoting available, accessible, and effective approaches for the management of overweight and obesity may improve overall industrial health by decreasing and preventing obesity and the subsequent risk of cardiovascular disease and diabetes,[38] osteoarthritis,[39] and spine diseases pertaining to obesity.[40]

TABLE 3. Multivariate-Adjusted Odds Ratios for Cases of New-Onset Sciatica

Factors	OR	95% CI	*P*
Age			
<40	1.00		
40–49	1.50	0.93–2.40	0.093
≥50	1.59	1.01–2.52	0.046
Sex			
Male	1.00		
Female	0.99	0.52–1.86	0.969
Obesity			
BMI <25 kg/m^2	1.00		
BMI ≥25 kg/m^2 (obese)	1.77	1.17–2.68	0.007
Mental workload (qualitative aspect)			
Not stressed	1.00		
Stressed	1.40	0.96–2.04	0.082

Data adjusted for age and sex.
CI indicates confidence interval; OR, odds ratio; BMI, body mass index.

Although not significant in multivariate analysis, mental workload in a qualitative aspect approached significance in crude analyses and was statistically significant in adjusted analyses ($P < 0.1$). Manual handling while under mental strain can biomechanically increase spine loads under experimental conditions.[41,42] As a result, the chance for injury, especially disc injury, increases, which may lead to the onset of sciatica. Existing literature on new-onset of sciatica relating to psychosocial factors is still scarce. Moreover, those results often conflict perhaps because different measurements were used to assess psychosocial factors. Further research is needed to elucidate the potential relationship fully between psychosocial factors and cases of new-onset sciatica.

There are some limitations to the study. Generalization of the results is an issue. First, approximately 89% of the study participants were male, and sex was an effect modifier, particularly in males. Although this study indicated that sex can be an effect modifier for obesity and mental workload, the number of females may not be sufficient to investigate effect modification. Further investigation is needed for effect modification in females. Second, there is also a concern that results may not represent workers who left work because of sciatica. Third, results may be influenced by selective drop out because 3194 workers followed-up were entered into the analysis out of 5310 participants. On the basis of the results comparing the baseline characteristics between the follow-up group and non–follow-up group (Table 1), more of the non–follow-up group were younger and engaged in no/less manual handling involved at work than the follow-up group. Although obesity

TABLE 4. Assessment of Effect Modification by Age and Sex on the Association of New-Onset Sciatica

Factor	OR	*P*	95% CI
Obesity (obese *vs*. not obese)			
<40	1.09	0.834	0.47–2.53
40–49	1.38	0.384	0.67–2.82
≥50	3.18	0.001	1.65–6.15
Obesity (obese *vs*. not obese)			
Male	1.93	0.002	1.26–2.95
Female	0.68	0.730	0.08–6.02
Mental workload (stressed *vs*. not stressed)			
<40	1.99	0.043	1.02–3.86
40–49	1.18	0.624	0.61–2.29
≥50	1.16	0.633	0.63–2.16
Mental workload (qualitative aspect) (stressed *vs*. not stressed)			
Male	1.44	0.071	0.97–2.13
Female	0.96	0.950	0.31–3.02

CI indicates confidence interval; OR, odds ratio.

and manual handling at work were statistically significant, the differences were practically small. This is perhaps because the number of both the follow-up and non–follow-up groups was large. Although it was assumed that these differences may not influence interpretation, results of the study may need to be regarded with care. Lastly, this study used the MLHW definition of obesity, unlike the previous literature using the World Health Organization definition of obesity. Although the MLHW definition may be appropriate for obese in Japanese population, not using an internationally-accepted definition of obesity may limit generalizing the findings.

Moreover, this study indicated effect modification by age exists in the association between obesity and new-onset sciatica, and the OR was high especially for those aged 50 or more. This can be explained by degenerated intervertebral discs and spinal canals by age, but further research may be needed for explaining this effect modification. Interpretation of the results regarding age is needed.

Additionally, misclassification at some extent is inevitable. Responses that rely on diagnosis and subjective measurement may be distorted because of the nature of the self-administered questionnaires, whereas retrospective questions may be distorted by recall bias. Future research should consider using both subjective as well as objective measures simultaneously.

Finally, there may be alternative methods for the selection of potential risk factors before conducting multivariate analysis. It should be noted that a more complicated model aside from including well-established potential confounders such as age and sex, may offer a better explanation of the data. Further research is needed to identify a full range of potential risk factors for inclusion in future studies.

CONCLUSION

The aim of this study was to examine risk factors, including psychosocial factors, for the development of sciatica in Japanese workers. In the study, individual factors such as age and obesity were identified as risk factors for the development of new-onset sciatica in previously asymptomatic individuals. Our findings suggest that the management of obesity is key to preventing new-onset sciatica. Japanese occupational health departments should encourage preventative strategies, including exercise, weight control, and control of dietary intake. Further research is needed to assess the effectiveness of obesity management in preventing new-onset sciatica.

➢ Key Points

- ❑ Significant associations between development of new-onset sciatica and age and obesity were found in both univariate and multivariate analyses.
- ❑ The relationship between individual and occupational factors and cases of new-onset sciatica is established, but the involvement of psychosocial factors in its development remains unclear. This study suggests that individual factors (*e.g.*, obesity) are the potential risk factors for new-onset sciatica in previously symptom-free workers.
- ❑ Our results suggest that reducing or preventing obesity may lower the risk of new-onset sciatica. Promoting available, accessible, and effective sources of weight management for workers should be encouraged in industrial health.

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ORIGINAL ARTICLE

Validity, reliability and responsiveness of the Japanese version of the Neck Disability Index

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Abstract
Background The Neck Disability Index (NDI) is one of the most widely used questionnaires for neck pain. The purpose of this study was to validate the Japanese NDI.
Methods We performed two surveys with an 8-week interval in 130 patients with neck pain, radiculopathy and myelopathy. We asked patients to answer two versions of the Japanese NDI: the original NDI, which had been completed by a forward–backward translation procedure, and the modified NDI, which has the phrase "because of neck pain" to the phase "because of neck pain or numbness in the arm." The other parameters examined were the strength of pain and numbness, the Japanese Orthopaedic Association Cervical Myelopathy Evaluation Questionnaire, the Hospital Anxiety and Depression Scale, and Short Form 36. Attending surgeons judged the symptom severity. Patients were asked to report the patient global impression of change (PGIC) at the second survey. The internal consistency, criterion-related and discriminative validity, and reliability were evaluated.
Results The original NDI and the modified NDI were 26.9 ± 17.1 and 29.9 ± 15.5, respectively. The Cronbach α values of the original NDI and the modified NDI were 0.92 and 0.89, respectively. Both versions of the NDI had good to excellent correlative coefficients with the related domains. The modified NDI had a higher validity for numbness and mental health-related QOL. The symptom severity was significantly correlated with the modified NDI. The intraclass correlation coefficients of the two surveys of the modified and original NDI were comparable. The effect sizes of the modified and the original NDI were 0.64 and 0.55, respectively. Spearman's ρ between the change of the NDI and the PGIC was 0.47 in the original NDI and 0.59 in the modified NDI.
Conclusions We demonstrated the validity, reliability and responsiveness of the Japanese NDI. The modified NDI was more strongly correlated with numbness and mental health-related QOL.

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Introduction

Neck pain is one of the most common complaints in the general population. Patient-reported outcome measures are primary tools used to assess the patients' condition, and the Neck Disability Index (NDI) [1], a symptom-specific questionnaire modified from the Oswestry Disability Index [2] for neck pain by Vernon, has been used extensively to evaluate patients with neck pain and cervical disorders [3].

There has been no report of the Japanese version of the NDI so far. The purpose of this study was to validate the Japanese version of the Neck Disability Index (NDI).

This study was supported by the Japanese Society for Spine Surgery and Related Research, and study approval was given by the institutional review board of the Clinical Research Support Center of the University of Tokyo Hospital.

Materials and methods

Translation of the NDI into Japanese

The NDI has ten questions with numerical responses on a six-point scale (0–5). The questions cover pain, personal care, lifting, reading, headaches, concentration, work, driving, sleeping and recreation. The raw total score of the NDI is calculated by summing the scores of the questions. The NDI is usually described as a percentage of raw scores divided by the full scores of answered questions. The final % score ranges from 0 to 100, and lower scores indicate a better state of health.

We translated the English NDI into Japanese by forward translation. The Japanese NDI was then successively translated into English as a back-translation. Finally, the original NDI was completed after we received suggestions from Dr. Vernon, the original developer of the NDI. However, during the preliminary survey at the university hospital, some patients with cervical disorders left comments on the questionnaire sheet indicating that their disability resulted not from neck pain, but from numbness in the arm. Therefore, we made the modified NDI (Supplementary material) by changing the phrase "because of neck pain" to the phase "because of neck pain or numbness in the arm" in the questions. Therefore, we included a comparative study between the two versions of the NDI in this validation study. We asked patients to answer both of the NDIs and then compared the validity between the two versions. The two Japanese versions of the original and modified NDI can be seen by downloading the files in the Supplementary material.

Participants

The first survey was performed in the hospital or in the clinic at six institutions after the institutional review board had approved the study. Signed informed consent was obtained from each patient. We recruited patients who had one of the three diagnoses below: (1) neck pain without neurological symptoms (the neck pain group), (2) cervical radiculopathy or (3) cervical myelopathy. The neck pain group included patients with acute and chronic neck pain without neurological symptoms. Patients who experienced pain after traffic vehicle accidents were included. A diagnosis of cervical radiculopathy (the radiculopathy group) was made when (1) a patient suffered from pain in an upper extremity and (2) arm pain was provoked by a specific head position or with a specific exercise, or a physician found an imaging abnormality related to the arm pain. Patients with pain only around the scapula were excluded. Cervical myelopathy (the myelopathy group) was confirmed from both the neurological and magnetic resonance imaging findings. Patients with rheumatoid arthritis, cerebral palsy and other systemic diseases that might have influenced neck conditions were excluded. Patients who suffered from both radiculopathy and myelopathy (radiculomyelopathy) were also excluded.

Data collection

The questionnaire set of the first survey included questions about patient backgrounds (age, sex, height, weight, occupation, marital status, education, smoking status) and previous treatment. It also included the original and modified versions of the Japanese NDI, the 11-grade strength of pain and numbness using a drawing of the body divided into six parts (Fig. 1), the Japanese Orthopaedic Association Cervical Myelopathy Evaluation Questionnaire (JOACMEQ) [4], the Hospital Anxiety and Depression Scale (HADS) [5, 6] and the Short Form 36 (SF-36) [7, 8].

The JOACMEQ is a disease-specific scale for cervical myelopathy proposed by the Japanese Orthopaedic Association. This patient-reported outcome measure has two components. The first component has 24 questions that comprise five domains: (1) cervical function, (2) upper extremity function, (3) lower extremity function, (4) bladder function and (5) quality of life (QOL). Each domain is calculated by a weighted sum of the involved questions, ranging from 0 to 100, with higher scores indicating a better health state. The second component has three visual analog scales for pain and numbness. We adopted only the first component in this study.

The HADS is a self-reported questionnaire for anxiety and depression. The HADS has 14 questions, and its total score ranges from 0 to 21 for each scale of anxiety and depression. A higher score indicates higher stress.

The SF-36 is a generic health-related QOL measure with 36 questions. The SF-36 consists of eight domains from the weighted sum of specific questions: physical functioning

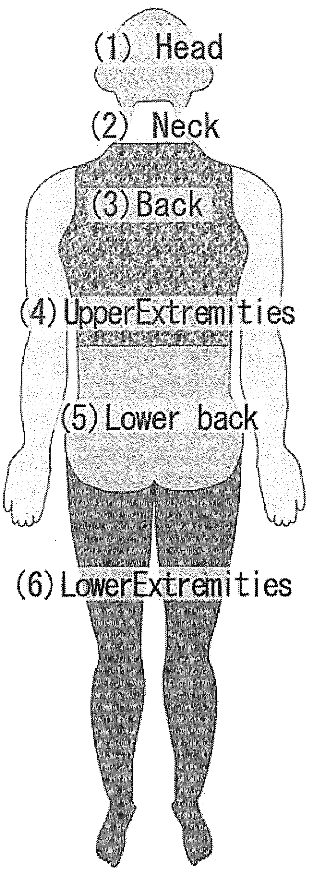

Fig. 1 The body part figure used for the question about the intensity of the pain and numbness

Table 1 Patient characteristics (n = 130)

	N	N %	Mean	SD
Height (cm)	129		163.0	8.5
Weight (kg)	129		64.4	12.7
BMI	129		24.2	3.8
Occupation				
Full-time job	59	46.9		
Part-time job	9	7.0		
Housemaker	20	15.6		
Retired	20	15.6		
Other	19	14.8		
Marital status				
Married	95	74.2		
Single	33	25.8		
Education				
Middle-school	8	6.3		
High school	53	41.4		
Training college	16	12.5		
University	42	32.8		
Graduate-school	4	3.1		
Other	5	3.9		
Smoking				
Never	50	38.5		
History of smoking	51	39.2		
Present smoker	29	22.3		
Related comorbidities				
Worker's compensation	1	0.8		
Diabetes mellitus	7	5.4		
Other	2	1.5		

Numbers do not always add up to the total number because of missing values

SD standard deviation, *BMI* body mass index

(PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social role (SF), role emotional (RE) and mental health (MH). The raw score of each domain ranges from 0 to 100, with higher scores indicating better health. Two representative scores are also calculated: the Physical Component Score (PCS) and the Mental Component Score (MCS), which are expressed in norm-based scoring. Each component score has the same mean and standard deviation (50 and 10, respectively) in a normal population.

We asked the attending surgeons to report diagnoses of the cervical disorders, symptom severity, comorbidities and treatment. The symptom severity judged by surgeons had three grades: severe, moderate and slight. The surveyed comorbidities were diabetic mellitus, shoulder disorder and peripheral nerve disorders.

The second survey for repeatability/responsiveness was performed by mail 8 weeks after the first survey. A question about the patient global impression of change (PGIC) was added in the questionnaire set. The PGIC was composed of seven answers: much better, better, slightly better, unchanged, slightly worse, worse and much worse.

Statistical analysis

Internal consistency, criterion-related validity and discriminative validity

The internal consistency was evaluated by the Cronbach α. In general, $\alpha \geq 0.9$ is regarded as excellent, $\alpha \geq 0.8$ as good and $\alpha \geq 0.7$ as acceptable [9]. The criterion-related validity was evaluated by calculating the correlation coefficients (Spearman's ρ) between two NDIs and other outcomes: the 11-grade severity of pain and numbness in body parts, JOACMEQ, HADS and the SF-36. In general, $\rho = 0.1$ is regarded as a weak association, $\rho = 0.3$ as a moderate association and $\rho = 0.5$ as a strong association [10]. The discriminative validity was evaluated by performing analysis of variance (ANOVA) between two versions of the NDI and the symptom severity.

Table 2 The outcomes of the first survey

	N	Mean	SD	Min	Median	Max
Japanese NDI (0–100)						
Original	118	26.9	17.1	0	26	72
Modified	118	29.9	15.5	0	28	70
Pain (0–10)						
Head	130	1.6	2.3	0	1	8
Neck	130	4.2	2.8	0	4	10
Back	128	3.0	2.7	0	2	10
Upper ext	128	3.5	2.9	0	3	10
Lower back	129	2.8	2.9	0	2	10
Lower ext	128	2.4	3.0	0	1	10
Numbness (0–10)						
Head	129	1.0	2.0	0	0	9
Neck	129	1.8	2.5	0	0	9
Back	126	1.7	2.4	0	0	10
Upper ext	128	3.9	2.8	0	4	10
Lower back	128	1.7	2.7	0	0	10
Lower ext	129	2.7	3.1	0	1	10
JOACMEQ (0–100)						
Cervical	127	60.0	27.8	0	62.5	100
Upper ext	129	84.3	19.1	0	85.7	100
Lower ext	126	74.6	22.8	16.7	75	100
Bladder	128	76.9	19.8	20	80	100
QOL	124	49.1	16.0	6.5	51.6	90.3
HADS (0–21)						
Anxiety	128	6.3	3.9	0	6	18
Depression	127	6.1	4.0	0	6	19
SF-36						
PF (0–100)	129	70.7	22.8	10	80	100
RP (0–100)	129	61.4	27.8	0	62.5	100
BP (0–100)	129	45.9	20.4	0	41	100
GH (0–100)	129	45.7	17.1	0	45	87
VT (0–100)	129	48.4	22.3	0	50	100
SF (0–100)	128	68.5	26.2	0	75	100
RE (0–100)	129	68.1	31.3	0	75	100
MH (0–100)	129	60.9	23.9	5	60	100
PCS	127	34.9	16.5	−10.1	38.2	63.4
MCS	127	45.2	11.6	14.6	46.3	75.1

SD standard deviation, *NDI* Neck Disability Index, *ext* extremity, *JOACMEQ* Japanese Orthopaedic Association Cervical Myelopathy Evaluation Questionnaire, *QOL* quality of life, *HADS* Hospital Anxiety and Depression Scale, *SF36* short form 36, *PF* physical functioning, *RP* role physical, *BP* bodily pain, *GH* general health, *VT* vitality, *SF* social role, *RE* role emotional, *MH* mental health, *PCS* Physical Component Score, *MCS* Mental Component Score

Reliability and responsiveness

The two versions of the NDI were evaluated by calculating the intraclass correlation coefficient (ICC) of first and second NDI in patients who reported being "unchanged" in the PGIC of the second survey. The ICC ranged from 0 to 1, and a higher value indicated higher repeatability. An ICC above 0.70 is accepted as good [11].

Responsiveness is the ability of an instrument to detect clinically relevant change over time. The responsiveness was evaluated from the data of patients who reported that they were "much better," "better" or "slightly better" in the PGIC of the second survey. We calculated the effect size and the standard response mean (SRM) from these data. The effect size was judged to be small if it was less than 0.2, moderate if it was around 0.5 and large if it was greater than 0.8 [10]. A higher SRM indicates higher responsiveness. We also calculated the correlation between change of the NDI and PGIC. Statistical analysis was performed by IBM SPSS 17.0 (IBM, Chicago, IL, USA).

Table 3 The Cronbach's α values of the original and modified NDIs

	Original NDI		Modified NDI	
	N	Cronbach α	N	Cronbach α
Neck pain	26	0.90	25	0.84
Radiculopathy	40	0.91	41	0.90
Myelopathy	52	0.94	52	0.92
Total	118	0.92	118	0.89

Results

The first survey was performed from March 2010 to October 2010, and 130 patients completed the first study. The mean patient age was 59.4 ± 13.8 years (range 22–88 years), and there were 88 male and 42 females. The patient characteristics are shown in Table 1. The pain duration averaged 50.3 ± 66.3 months. The interval between the two surveys averaged 56.9 ± 5.6 days. Thirty-four (26.2 %) patients had received no treatment before the first survey, and of the others who had previous or ongoing treatment, 89 (68.5 %) received therapeutic drugs, 59 (45.4 %) had surgery, and 11 (8.5 %) received physical therapy (% greater than 100 because of multiple choices). The symptom severity judged by surgeons was mild in 44 (33.9 %), moderate in 70 (53.9 %) and severe in 16 (12.3 %) patients.

Twenty-eight (21.5 %) patients were classified into the neck pain group, 45 (34.6 %) into the radiculopathy group and 57 (43.9 %) into the myelopathy group. The number of patients who underwent surgical treatment after the first survey was 1 (3.6 %) in the neck pain group, 7 (15.6 %) in the radiculopathy group and 6 (10.5 %) in the myelopathy group.

The original NDI and the modified NDI of the first survey were 26.9 ± 17.1 and 29.9 ± 15.5, respectively (Table 2). No response was frequently found (6.9 and 8.5 %, respectively) for the question about driving. The ceiling effect of individual questions was small (0 to 4.8 %), but the floor effect was found more frequently in the original NDI than in the modified NDI (5.1 vs. 0.9 %). In both NDIs, the floor effect was significant for question 5 (about headaches) and 9 (about sleep) (45.3–50.8 %). The results of the NRSs, JOACMEQ, HADS and SF-36 are shown in Table 2.

In the second survey, 118 patients responded. The response to the PGIC was "much better" in 7 (5.9 %) patients, "better" in 24 (20.3 %), "slightly better" in 21 (17.8 %), "unchanged" in 55 (46.6 %), "slightly worse" in 5 (4.2 %), "worse" in 5 (4.2 %) and "much worse" in 1 (0.9 %) patient.

Internal consistency, criterion-related validity and distinctive validity

The Cronbach α of the original NDI and the modified NDI were 0.92 and 0.89, respectively (Table 3). The subgroup analysis of the three groups showed good to excellent values for Cronbach's α.

The majority of parameters had a statistically significant correlation with the NDIs (Table 4). The original NDI had higher CCs for pain severity in the neck and back. The modified NDI had a higher correlation than the original NDI in some domains: numbness in the upper extremities, lower back and lower extremities; the upper/lower extremity function in the JOCMEQ; all mental health domains and the MCS in the SF36.

There was a statistically significant difference in the symptom severity for the modified NDI (ANOVA, $p = 0.020$), but not for the original NDI ($p = 0.142$).

Reliability and responsiveness

A total of 118 patients responded to the PGIC questionnaire, and 55 patients (46.6 %) answered "unchanged" in the PGC in the second survey. Their responses were analyzed for the test–retest repeatability. The ICC of the original and modified NDI was accepted as good (0.77 and 0.78, respectively).

Spearman's ρ between the two versions of the NDI and the PGIC was 0.47 ($p < 0.0001$) in the original NDI and 0.59 ($p < 0.0001$) in the modified NDI (Fig. 2).

Fifty-two patients (44.1 %) reported a positive change at the second survey ("much better," "better" and "slightly better"). The effect size of the original and modified NDI was judged to be moderate (0.55 and 0.64, respectively). The SRMs of the original and modified NDI were −0.52 and −0.66, respectively.

Discussions

Our study demonstrated that both of the Japanese NDIs had good to excellent validity, repeatability and responsiveness.

We compared the internal consistency and repeatability of the Japanese NDI with the NDIs in other languages (Table 5) and found that the internal consistency of the Japanese NDI was comparable to the NDI in other languages. The reliability was marginally acceptable, possibly

Table 4 Correlations between the two versions of the NDI and other outcomes

	N	Original NDI		Modified NDI	
		Spearman	*p* value	Spearman	*p* value
Pain (0–10)					
Head	118	0.374	<0.0001	0.370	<0.0001
Neck	118	0.635	<0.0001	0.486	<0.0001
Back	117	0.601	<0.0001	0.555	<0.0001
Upper ext	117	0.455	<0.0001	0.499	<0.0001
Lower back	117	0.221	0.017	0.219	0.018
Lower ext	117	0.271	0.003	0.319	0.001
Numbness (0–10)					
Head	118	0.306	0.001	0.347	<0.0001
Neck	118	0.435	<0.0001	0.443	<0.0001
Back	115	0.407	<0.0001	0.416	<0.0001
Upper ext	116	0.402	<0.0001	0.481	<0.0001
Lower back	117	0.256	0.001	0.327	<0.0001
Lower ext	117	0.286	<0.0001	0.371	<0.0001
JOACMEQ (0–100)					
Cervical	116	−0.397	<0.0001	−0.369	<0.0001
Upper ext	117	−0.385	<0.0001	−0.454	<0.0001
Lower ext	115	−0.363	<0.0001	−0.427	<0.0001
Bladder	118	−0.191	0.039	−0.206	0.026
QOL	115	−0.677	<0.0001	−0.686	<0.0001
HADS (0–21)					
Anxiety	116	0.415	<0.0001	0.414	<0.0001
Depression	117	0.426	<0.0001	0.455	<0.0001
SF36					
PF (0–100)	117	−0.526	<0.0001	−0.551	<0.0001
RP (0–100)	117	−0.599	<0.0001	−0.607	<0.0001
BP (0–100)	117	−0.64	<0.0001	−0.669	<0.0001
GH (0–100)	117	−0.501	<0.0001	−0.510	<0.0001
VT (0–100)	117	−0.518	<0.0001	−0.597	<0.0001
SF (0–100)	116	−0.422	<0.0001	−0.483	<0.0001
RE (0–100)	117	−0.523	<0.0001	−0.580	<0.0001
MH (0–100)	117	−0.413	<0.0001	−0.482	<0.0001
PCS	115	−0.602	<0.0001	−0.617	<0.0001
MCS	115	−0.336	<0.0001	−0.410	<0.0001

NDI Neck Disability Index, *Ext* extremity, *JOACMEQ* Japanese Orthopaedic Association Cervical Myelopathy Evaluation Questionnaire, *QOL* quality of life, *HADS* Hospital Anxiety and Depression Scale, *SF36* short form 36, *PF* physical functioning, *RP* role physical, *BP* bodily pain, *GH* general health, *VT* vitality, *SF* social role, *RE* role emotional, *MH* mental health, *PCS* Physical Component Score, *MCS* Mental Component Score

because of the long interval between the two surveys; the interval between the two surveys ranged from 1 day to 2 weeks in other studies except for one subgroup. We selected an 8-week interval between the two surveys because we had planned to evaluate both the repeatability and responsiveness by separating patients into two groups based on the PGIC of the second survey.

The majority of past reports demonstrated the validity of the NDI in the neck pain population. Few validation studies of the NDI were performed in patients with cervical radiculopathy/myelopathy, who do not always have neck pain, though many studies have adopted the NDI as an assessment following conservative or surgical treatment. With regard to the patients with radiculopathy, only Cleland et al. [13] reported a good test–retest reliability (ICC = 0.68) in 38 radiculopathy patients. The Korean NDI developed by Song et al. [21] demonstrated the validity and reliability in a mixed population that included radiculopathy and myelopathy patients.

Patients who have neurological symptoms often complain not only of pain but also variable symptoms: tingling, burning, numbness, etc. Patients with spinal disorders often complain of numbness and insist that it is different from pain, although numbness is usually regarded as one of the symptoms of neuropathic pain [23]. In a study of 892 patients with cervical ossification of the posterior

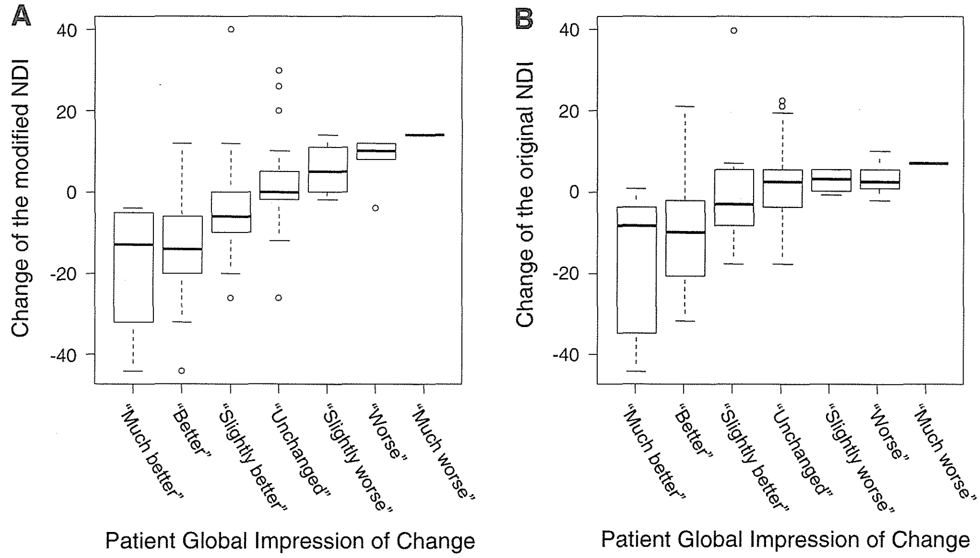

Fig. 2 The relationship between the change in the NDI and the patient global impression of change (PGIC). **a** The modified NDI: Spearman's $\rho = 0.588$ ($p < 0.0001$, $n = 106$). **b** The original NDI: Spearman's $\rho = 0.467$ ($p < 0.0001$, $n = 106$)

Table 5 The internal consistency and reliability of the NDI in various languages

	N	Condition	Cronbach α	ICC/interval
English [1]	52	Neck pain	0.8	0.89/2 days
French [12]	101	Neck pain	na	0.93/1 day
Swedish [13]	59	Neck pain	na	0.97/2 days (chronic)
				0.94/3 months (chronic)
				0.89/2 days (acute)
Dutch [14]	187	Acute neck pain	na	0.90/1 week
Brazilian Portuguese [15]	203	Trauma, OA	0.74	0.92/1 day
				0.48/1 week
Greek [16]	65	Neck pain	0.85	0.93/1–2 weeks
Iranian [17]	185	Neck pain	0.88	0.90/2 days
Catalan [18]	150	Whiplash	0.87	na
Spanish [19]	221	Neck pain	0.89	0.88/2 weeks
Turkish [20]	88	Chronic neck pain	na	0.979
Korean [21]	78	Radiculopathy (50)	0.82	0.93/2 days
		Myelopathy (28)		
Chinese [22]	125	Neck pain	0.89	0.95/1 day
Japanese (present study)	130	Neck pain (28)	0.92 (original)	0.77/8 weeks (original)
		Radiculopathy (45)	0.89 (modified)	0.78/8 weeks (modified)
		Myelopathy (57)		

NDI Neck Disability Index, *na* not available, *OA* osteoarthritis

longitudinal ligament [24], the researchers had asked, "Which is more troublesome, pain or numbness?" Of these patients, 45.0 % responded "both pain and numbness," 25.0 % responded "numbness" and 22.2 % responded "pain." Their result indicates the clinical importance of numbness, which is often regarded by patients as another entity different from pain. In the present study, the modified NDI had a higher criterion-related validity in numbness and mental health-related QOL, while the original NDI had a higher criterion-related validity in neck pain. In other words, the inclusion of numbness in the questionnaire enhanced the validity of the NDI in the assessment of patients with cervical disorders. In addition, the modified NDI had a higher correlation with the assessment by both physicians and patients and had a higher effect size and SRM than the original NDI. Accordingly, the modified NDI may be a better choice for studies of patients with cervical disorders. On the other hand, the original NDI is still useful for epidemiological studies of nonspecific neck pain.

In summary, we demonstrated the validity, reliability and responsiveness of both versions of the Japanese NDI, and the modified NDI more accurately reflected the numbness and mental health-related QOL, while the original NDI better reflected the neck pain.

Conflict of interest The authors declare that K. Takeshita received payment for lectures that had no direct relationship with the submitted work from Pfeizer Japan Inc., Tokyo, Japan.

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ORIGINAL ARTICLE

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 $\geq$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 $\geq$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 $\geq$5 and women with a score $\geq$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)/height^2 (m^2)] 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)	*P* value	HR (95 % CI)	*P* value	HR (95 % CI)	*P* 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-

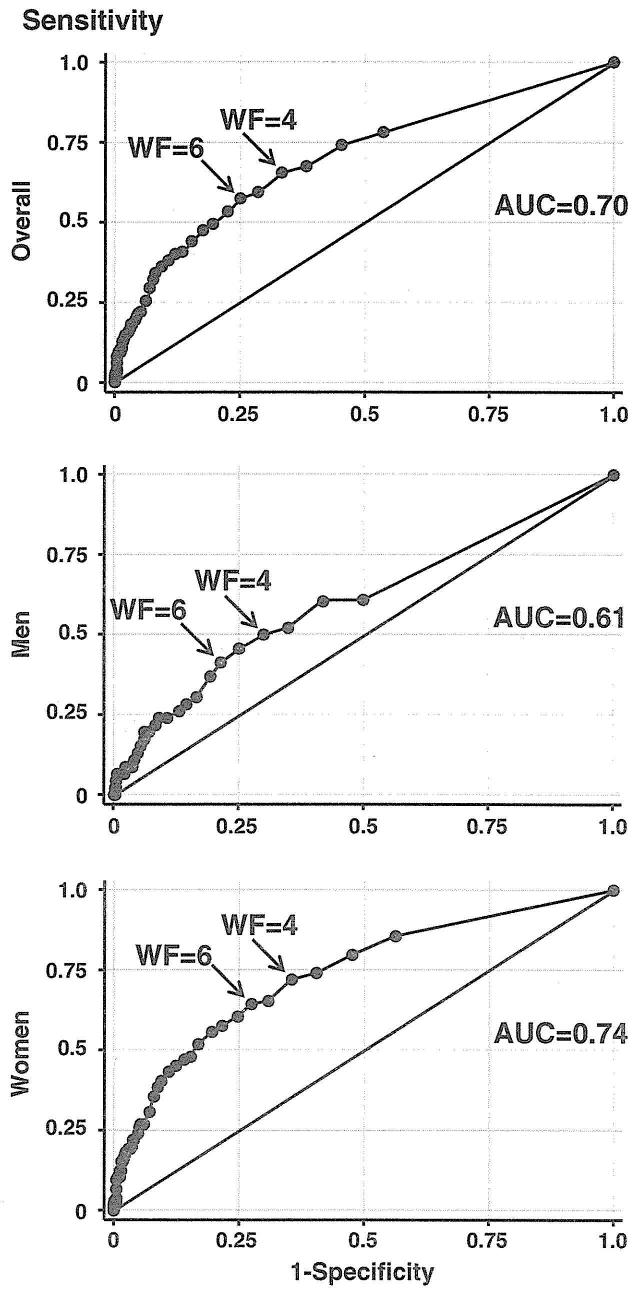

Fig. 1 Receiver operating characteristic (ROC) curve analysis for discriminating the occurrence group of certified need of care in the overall population, in men, and in women. *AUC* area under ROC curve, *WF* WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) function score

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