

Data analysis

The outcome of interest was new-onset LBP with disability during the 2-year follow-up period.

At least one new-onset at either 1 year or 2 years was counted as an event; thus, 1-year and 2-year follow-up outcomes were combined into one composite score. In this study, LBP with disability was defined as LBP with work interference, with or without sick-leave due to LBP, which was categorized into either “grade 2” or “grade 3”. Incidence was calculated for the participants who reported no LBP (grade 0) during the past year at baseline (1-year symptom-free participants). Participants were excluded from the analysis if they changed their job for reasons other than LBP, or developed LBP due to a traffic accident, a tumor, including metastasis, infection, or fracture.

In addition to the compilation of simple descriptive statistics, logistic regression was used to explore the associations between risk factors and new-onset LBP with disability. Results of logistic regression analysis were summarized by odds ratios (ORs) and the respective 95% confidence intervals (CIs). For the assessment of potential risk factors, crude and adjusted ORs were initially estimated. Age, gender, and previous episodes of LBP were included in the regression model because age and gender are well-established confounders, and because previous episodes of LBP is one of the strongest predictors of new-onset LBP.¹⁰ Subsequently,

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multivariate logistic regression analyses were conducted including the original confounders as well as all the factors that were significant predictors of LBP incidence in initially estimated crude and adjusted ORs. Statistical significance was assumed at the 5% level if the 95% CI did not overlap 1. All statistical calculations were carried out with the software package STATA 9.0.

[Results]

Baseline characteristics of the study participants

Of the 3,194 participants who responded to both the 1-year and 2-year follow-up questionnaires, 836 reported no LBP during the past year at baseline (1-year symptom-free) and were included in subsequent analyses (Figure 1). The mean (SD) age of participants was 44.2 (10.2) years and the majority were male (n=738; 88.3% with one missing value). Participants had a mean BMI of 23.1 (2.9) kg/m². A total of 636 participants (76.1%) were categorized as not manually handling any objects in their work, while 83 (9.9%) were manually handling <20-kg objects, 91 (10.9%) were manually handling ≥20-kg objects or were working as a caregiver, and 26 (3.1%) were missing data. The most common occupations in the non-manual handling category, the manual handling of <20-kg objects, and the manual handling of ≥20-kg objects or working as a caregiver category were desk work, manufacturing/engineering, and nursing.

Incidence of new-onset low back pain with disability

Of the 836 eligible participants, 308 (36.8%) reported a new episode of LBP during the 2-year follow-up period. The proportion of new LBP incidents according to grade were as follows: grade 1 (n=275), grade 2 (n=22), and grade 3 (n=11). Thus, the incidence of new-onset LBP with disability, defined as grade 2 or 3, was 3.9%. Of the 33 participants reporting new-onset LBP with disability, 20 (60.6% with six missing values) reported sudden onset, and 6 (18.2% with one missing value) have developed chronic back pain (lasting ≥ 3 months). In the participants with grade 3 LBP, the median duration of sick-leave was 3 days (range: 1 to 15 days).

Association between new-onset of low back pain with disability and potential risk factors

Crude and adjusted ORs (adjusted for age, gender, and previous episodes of LBP) for the onset of LBP and their 95% CIs are shown in Table 1. The previous episodes of LBP were significantly associated with about a three-fold higher risk of onset of LBP in the crude analysis. In both crude and adjusted analyses, statistically significant associations with LBP occurrence were found for lifting, monotonous work, and stress of interpersonal relations at workplace, with each factor increasing risk by a factor of 2 to 4. After the assessment from a clinical perspective, finally, all of these factors were included in the same model to adjust for the other factors, as well as age and gender. As shown in Table 2, all of the factors remained statistically significant or almost

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significant in the multivariate analysis, and the magnitudes of ORs did not markedly change from both crude and adjusted analyses.

[Discussion]

Our results indicated that, in addition to previous episodes of LBP, psychosocial factors and work-related physical demands were important predictors of disabling LBP risk after 1-year symptom-free period among Japanese workers. Similar findings have been reported in several Western countries.^{10,29,30,31} Disability has been recognized to result from an interaction between biological, psychological and social aspects, as encompassed in the biopsychosocial model.^{10,29} To our knowledge, this study is the first to suggest that the biopsychosocial model also applies to the development of LBP disability among Japanese workers.

In this study, the intensity of LBP was determined by self-report using an original 4-point grading scale. The grades were strongly correlated with the Oswestry Disability Index (ODI), a well-known disease-specific scale ($\rho=0.75$). Additionally, in an effort to aid in the proper self-assessment of LBP, a diagram of the lower back was included in the questionnaire to specify the area of LBP. Our experience suggests that not only should the LBP area be illustrated in a diagram but also should pain be characterized according to the resulting limitations or changes in usual activities and daily routine. These efforts may help address the lack of standardization in

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epidemiological research.³²

LBP with disability was chosen as the outcome of interest to explore risk factors for new-onset LBP in the present study, as the assessment of severe LBP was considered more critical to both individuals and society in terms of health, workplace productivity, and healthcare cost. Although absence from work is often used as outcome measurement for disability in Western countries, disabling LBP in the current study was defined as LBP that interfered with work, regardless of sick leave. This was because the number of participants who took sick-leave due to disability was relatively small and both groups of people either absent or not absent from work shared similar median ODI values (data not shown). Our international epidemiological study previously showed that a sick-leave attributed to musculoskeletal disorders, predominantly LBP, appears to be much less common among Japanese workers than British workers.³³ The lower percentage of Japanese workers taking sick-leave due to disability compared to European countries may be a result of cultural differences towards one's work. Adding together both proportion of people leading and not leading to sick-leave in Japanese workers with disability was in turn almost equal to the proportion of those on sickness absence in UK. Therefore, when assessing Japanese workers, it seems reasonable to define LBP disability as LBP with work interference, with or without sick-leave.

The present study focused on LBP incidence among participants who were symptom free

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during the preceding year. Studies suggest that LBP is commonly recurrent.⁵⁻⁸ Indeed, reported rates of recurrence in the first year after the episode vary between 24% and 87%.³⁴⁻³⁸ Due to the high recurrence rate, the required duration of a symptom-free period for entry into research studies is typically between 1 to 3 months.³⁹ However, we sought to determine whether previous episodes of LBP would remain a predictor of future back pain even when subjects were symptom-free for at least a year. In this study, 3.9% of the participants had a new incident of disabling LBP during the 2 years of follow-up. The relatively low incidence of LBP in the current study may be a result of the strict definition of LBP disability as well as the requirement of a 1-year symptom-free period at study entry.

Our study results showed that previous episodes of LBP significantly increased the risk of a new episode of LBP disability, despite being symptom-free for more than one year. As previously reported,⁴⁰ frequent lifting was also a significant potential risk factor for LBP. Of the incident cases, 74.1% were of sudden onset, suggesting that the major cause of disability could be injury. Lifting tasks appeared to be reasonable for the risk of new-onset because physical movements may lead to injury. In contrast, in agreement with other studies,^{41,42} a sedentary lifestyle was not associated with LBP disability. In this analysis, psychosocial factors, such as monotonous work and stress of interpersonal relations in the workplace, predicted risk of LBP after controlling for other variables. Another epidemiological survey also demonstrated that

future LBP was strongly associated with stressful and monotonous work.³⁰ Although it is not intuitively understandable why work-related stress is a cause of LBP, biomechanical research suggests that psychological stress can contribute to an increased spinal loading and ultimately can increase the risk of injury.³¹

Although only four factors were chosen for the final multivariate analysis according to the predefined selection criteria, other factors also showed a trend for association with LBP. For example, frequent bending showed a notable effect on risk of LBP in univariate analysis. However, bending was highly correlated with lifting ($\rho=0.51$). Due to collinearity, only one of these factors could be included in the multivariate model. In this case, lifting was chosen because ergonomic solutions could be more readily provided for lifting tasks. Moreover, a number of psychosocial factors, including job control, job fitness, vigor, and anxiety, nearly satisfied the criteria for entry into multivariate analysis. A post-hoc analysis was performed by stepwise selection of these variables along with the other significant factors. Ultimately, only the same four factors, selected based on the predefined procedures, remained in the final model (data not shown).

Unexpectedly, our findings appeared similar to those in Western countries. Initially, due to cultural differences, we expected that some potential risk factors would probably be different from elsewhere. The Westernization of Japanese culture may be reflected in the results of this

analysis. Otherwise, the questionnaire may have simply not included factors that would have shown potential differences from other countries or cultures. Further investigation will be required to provide more precise reasons.

Limitations of this study warrant mention. First, the generalizability of findings is limited due to the sample included. For instance, the proportion of female participants was too small to be considered a representative sample of the total workforce, suggesting that the findings be treated with caution. Additionally, since the study was designed to recruit currently working people, those who had left the workforce due to LBP were excluded from the analysis, thereby potentially leading to an underestimation of disabling LBP. Another concern is selective drop-out. Of 5,310 participants, 3,914 were followed up on and entered into the analysis. This may introduce bias into the data analysis. To assess the effect of the selective drop-out, the baseline characteristics of participants who were followed up on and those who dropped out are calculated. The mean (SD) age was 43.4 (10.1) years and 38.5 (10.2) years, respectively, and the majority were male in both groups (80.7% vs 82.3%). Those who completed the study had mean (SD) BMI of 23.1 (3.2) while the values for dropouts were 23.0 (4.0). In the follow-up group (vs the drop-out group), 69.9% (vs 62.1%) were categorized as not manually handling any objects in their work, while 9.5% (vs 13.2%) were manually handling <20kg objects, 16.9% (vs 19.7%) were manually handling \geq 20kg objects or were working as a caregiver, and 3.7% (vs 5.0)% were

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missing data. In both groups, the most common occupational fields in the categories of non-manual handling of objects, the manual handling of <20kg objects, and the manual handling of ≥20kg objects or working as a caregiver were desk work, manufacturing/ engineering and nursing, respectively. We considered that the baseline characteristics of both groups appeared to be not much different. Second, due to the nature of a self-assessment survey, some degree of misclassification is inevitable. Ideally, physical workload should be assessed by means of objective measures. Moreover, the survey questionnaire contained retrospective questions, so the possibility for recall bias should be kept in mind. Third, although the cognitive and emotional aspects of backache are known to have an effect on developing serious disability,⁴³ some important factors (e.g. fear-avoidance belief) were not evaluated in this study because appropriate questionnaires were not available in Japanese. Future studies should include self-report outcome measures, such as the Fear-Avoidance Belief Questionnaire (FABQ)⁴⁴ or the Tampa Scale of Kinesiophobia (TSK)^{45,46} to assess the impact of these factors in Japanese workers. The Japanese versions of these questionnaires are now being developed. Lastly, the strategy of pre-selection for potential risk factors was not absolute. Although sex and age, which are known as well-established confounders, were included into the model, a more complicated model could explain the data better. Further assessment may help confirm these findings and find other potential risk factors.

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In conclusion, our results suggest that ergonomic as well as psychosocial factors play a significant role in the development of future back pain disability after more than 1-year symptom-free period among Japanese workers. Previous studies have shown that a merely ergonomic intervention is not effective in preventing LBP.⁹ Thus, both ergonomic and psychosocial factors should be addressed in workplace strategies aimed at preventing the new onset of LBP disability.

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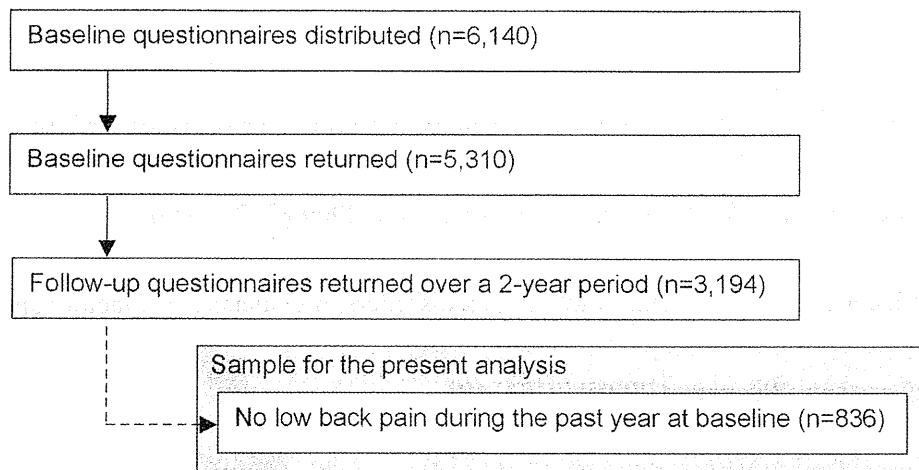


Table 1. Crude and adjusted odds ratios of baseline factors for the new onset of low back pain with work disability

Factors	%	Crude OR	95%CI	Adjusted OR	95%CI
Age (Years)					
< 40	35.5	1.00			
40-49	29.4	1.36	0.57-3.26		
≥ 50	35.1	1.27	0.54-2.99		
Gender					
Male	88.4	1.00			
Female	11.6	0.79	0.24-2.65		
Previous episodes of LBP					
No	59.8	1.00			
Yes	40.2	3.12	1.49-6.54		
Obesity ^a					
< BMI 25 kg/m ²	77.3	1.00		1.00	
≥ BMI 25 kg/m ² (obesity)	22.7	0.96	0.41-2.25	0.92	0.38-2.18
Smoking habits ^b					
Non-heavy smoker	70.3	1.00		1.00	
Heavy smoker	29.7	1.55	0.74-3.25	1.43	0.62-3.28
Education					
College/University	71.5	1.00		1.00	
High school/Junior high school	28.5	1.07	0.48-2.37	1.08	0.47-2.45
Exercise habits					
≥ Once per week	36.4	1.00		1.00	
< Once per week	63.6	1.09	0.52-2.30	1.22	0.57-2.61
Flexibility ^c					
Flexibility	76.9	1.00		1.00	

Factors	%	Crude OR	95%CI	Adjusted OR	95%CI
Not flexible	23.1	0.79	0.32-1.97	0.78	0.31-1.95
Experience of current job					
< 5 years	31.3	1.00		1.00	
≥ 5 years	68.7	1.43	0.64-3.22	1.40	0.62-3.17
Working hours per week ^d					
< 60 hours	86.0	1.00		1.00	
≥ 60 hours	14.0	1.08	0.41-2.86	1.10	0.41-2.98
Work shift					
Daytime shift	86.4	1.00		1.00	
Nighttime shift	13.6	2.05	0.90-4.66	2.18	0.94-5.10
Employment status					
Full-time worker	95.4	1.00		1.00	
Other workers	4.6	1.35	0.31-5.87	1.34	0.29-6.19
Manual handling at work					
No manual handling (Desk work)	78.5	1.00		1.00	
Manual handling of < 20-kg objects	10.3	1.35	0.45-3.99	1.36	0.45-4.11
Manual handling of ≥ 20-kg objects or working as a caregiver	11.2	1.25	0.42-3.69	1.26	0.40-3.92
Bending ^e					
Not frequent	94.8	1.00		1.00	
Frequent	5.2	2.82	0.94-8.44	3.15	1.02-9.75
Twisting ^e					
Not frequent	97.1	1.00		1.00	
Frequent	2.9	2.30	0.52-10.27	2.59	0.56-12.05
Lifting ^e					
Not frequent	95.7	1.00		1.00	
Frequent	4.3	3.29	1.09-9.94	4.22	1.32-13.50
Hours of desk work ^f					
< 6 hours per day	45.7	1.00		1.00	
≥ 6 hours per day	54.3	0.64	0.31-1.30	0.63	0.30-1.28
Mental workload (quantitative aspect) ^g					
No stress	58.3	1.00		1.00	
Stress	41.7	0.89	0.44-1.82	0.85	0.41-1.78
Mental workload (qualitative aspect) ^g					
No stress	59.3	1.00		1.00	
Stress	40.8	1.58	0.79-3.18	1.58	0.78-3.22
Physical workload ^g					
No stress	71.2	1.00		1.00	
Stress	28.9	1.44	0.70-2.98	1.71	0.81-3.61

Factors	%	Crude OR	95%CI	Adjusted OR	95%CI
Interpersonal stress at work ^g					
No stress	83.7	1.00		1.00	
Stress	16.3	2.42	1.12-5.21	2.60	1.18-5.75
Work environmental stress ^g					
No stress	79.1	1.00		1.00	
Stress	20.9	0.69	0.26-1.81	0.69	0.26-1.84
Job control ^g					
Controlled	86.0	1.00		1.00	
Not controlled	14.1	2.03	0.89-4.62	2.20	0.94-5.11
Utilization of skills and expertise ^g					
Utilization of skills and expertise	84.3	1.00		1.00	
No utilization of skills and expertise	15.7	1.78	0.78-4.03	1.91	0.82-4.43
Job fitness ^g					
Feeling fit	79.4	1.00		1.00	
Not feeling fit	20.7	1.99	0.95-4.20	1.98	0.93-4.21
Job satisfaction ^g					
Satisfied	80.8	1.00		1.00	
Not satisfied	19.2	1.59	0.73-3.50	1.59	0.72-3.54
Vigor ^g					
Vigorous	89.1	1.00		1.00	
Not vigorous	10.9	2.27	0.95-5.38	2.23	0.92-5.39
Anger ^g					
Not angry	76.1	1.00		1.00	
Angry	23.9	1.62	0.77-3.41	1.64	0.76-3.54
Fatigue ^g					
Not fatigue	78.3	1.00		1.00	
Fatigue	21.7	0.63	0.24-1.65	0.63	0.23-1.69
Anxiety ^g					
Not anxious	82.6	1.00		1.00	
Anxious	17.4	2.13	0.99-4.58	2.06	0.94-4.51
Depressed mood ^g					
Not feeling depressed	76.7	1.00		1.00	
Depressed	23.3	1.07	0.47-2.41	1.01	0.44-2.31
Somatic symptoms ^g					
No somatic symptoms	87.8	1.00		1.00	
Somatic symptoms	12.2	0.74	0.22-2.47	0.59	0.18-2.01
Support by supervisors ^g					
Support	77.4	1.00		1.00	
No support	22.6	1.60	0.74-3.45	1.50	0.69-3.25
Support by coworkers ^g					
Support	66.5	1.00		1.00	
No support	33.5	0.90	0.42-1.92	0.93	0.43-2.01

Factors	%	Crude OR	95%CI	Adjusted OR	95%CI
Support by family or friends ^g					
Support	83.4	1.00		1.00	
No support	16.7	1.16	0.47-2.87	1.11	0.44-2.81
Daily-life satisfaction ^g					
Satisfied	76.8	1.00		1.00	
Not satisfied	23.2	1.70	0.81-3.57	1.80	0.84-3.84
Monotonous work ^h					
Not monotonous	83.9	1.00		1.00	
Monotonous	16.1	2.34	1.09-5.05	2.58	1.18-5.64
Family history of LBP with disability					
No LBP with disability	85.8	1.00		1.00	
LBP with disability	14.2	1.78	0.75-4.23	1.75	0.73-4.21

OR: Odds ratio, CI: Confidence interval, BMI: body mass index, LBP: low back pain

Adjusted for age, gender, and previous episodes of low back pain.

^a Obesity: BMI of ≥ 25 is defined as obesity in Japan.

^b Smoking habits: Brinkmann index, calculated from the total number of cigarettes smoked per day multiplied by duration of smoking in years, of ≥ 400 was defined as heavy smoker.²⁷

^c Flexibility: flexibility was determined if wrists could reach beyond the knees, but fingertips could not reach the ankles.²⁸

^d Working hours: ≥ 60 hours per week of uncontrolled overtime.

^e Bending, twisting, lifting: \geq half of the day as frequent.

^f Hours of desk work: longer than 6 hours was determined as static posture.

^g Work-related stress factors assessed with the brief job stress questionnaire: not feeling stressed, feeling stressed: the 5 original responses were reclassified into “not feeling stressed”, where low, slightly low and moderate were combined, and “feeling stressed”, where slightly high and high were combined.

^h Monotonous task: feelings of monotony or boredom at work.