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ORIGINAL ARTICLE

The normative score and the cut-off value of the Oswestry Disability Index (ODI)

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Abstract
Purpose The Oswestry Disability Index (ODI) is one of the most common scoring systems used for patients with low back pain (LBP). Although the normative score of the ODI was reported to be 10.19 in a review article, no study has calculated the normative score after adjusting the value based on the age distribution. In addition, none of the previous studies has estimated the cut-off value which separates LBP with disability from LBP without disability. The purpose of this study was to estimate the normative score by adjusting the data for age distribution in Japan, and to determine the cut-off value which separates LBP with disability from LBP without disability.
Methods We conducted an internet survey on LBP using the Japanese version of the ODQ. A total of 1,200 respondents, composed of 100 males and 100 females in each age group (from the 20s to 70s), participated in this study. We also asked them to provide information about their backgrounds. We estimated the normative score after correcting for the age distribution of Japan. We also estimated the ODI of those with or without disability, the factors associated with the ODI, and the cut-off value which separates LBP with disability from LBP without disability.
Results The participants' backgrounds were similar to the national survey. The normative score of the ODI was estimated at 8.73. The ODI of the LBP with disability group was 22.07. Those with sciatica and obese subjects showed higher ODI than those without. The optimal cut-off value was estimated to be 12.
Conclusions We defined the normative score and the cut-off value of the ODI.

Keywords The Oswestry Disability Index (ODI) · Normative score · Cut-off value · Internet survey

Introduction

Most adults experience some degree of low back pain (LBP) at some point in their lives, and approximately 85–90% has been classified as "non-specific LBP" [1]. As in many industrialized countries, LBP is one of the most common health disabilities in Japan. The one-month prevalence was 30.6% in a population-based survey [2]. Therefore, the low back is the most common area with pain reported in the research studies on chronic pain [3, 4].

The Oswestry Disability Questionnaire (ODQ) has been one of the most commonly used disease-specific measures for patients with LBP [5]. The Oswestry Disability Index (ODI) is calculated based on each score of the ODQ, which consists of ten items. Each of the ten items is scored from 0 to 5, and the total is added and multiplied by 2. Therefore, the ODI ranges from 0 to 100. A higher score on the

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ODI indicates a more severe disability caused by LBP. The ODQ has been translated into many languages [6], including Japanese in 2003 [7].

The normative score of the ODI was reported to be 10.19 in a review article by Fairbank et al. [6]. However, no study has calculated the normative score after adjusting the value by the age distribution. In addition, the cut-off values were only reported as the change between before and after the therapy [8–10].

To estimate the normal score of the ODI, calculating the score from a "normal" pain-free population seems logical, but its clinical significance is doubtful, because LBP itself is common at some point in most of the population, regardless of sex or age. The severity of pain correlates with disability, as shown by von Korff et al. [11], and the present goal of LBP treatment is to help patients to become or remain free from disability. Therefore, we think that estimating a cut-off value which discriminates between people with no or mild LBP without disability and people with disability would be clinically meaningful.

The purpose of this study was to estimate the normative score of the ODI by adjusting the data based on the age distribution in Japan, and to estimate the cut-off value of the ODI which separates patients with LBP with disability from LBP without disability.

Materials and methods

We conducted an internet survey on LBP using a Japanese version of the ODQ [7]. Two validated versions of the Japanese ODI are available [7, 12]. We chose Fujiwara's version, which was translated from the ODI version 2.0, except that distances were not expressed in miles, but in kilometers, for the questions in Sect. 4. The reliability and validity of this version was evaluated in their previous study, and was sufficient to use for outcome studies in Japan. We asked 13,180 people to participate in this study by e-mail with the assistance of a single internet research company. The company has 1,888,778 registered members, and we chose members sequentially with a legitimate method for random sampling of the company. Finally, a total of 1,200 participants, composed of 100 males and 100 females in each age group (20s, 30s, 40s, 50s, 60s and 70s), were selected from different regions for the study in October 2010, and all of them voluntarily participated in the research study on a first-come, first-served basis. There was no missing data, because the participants could not finish the questionnaire in the web browser until all questions had been answered. The participants received points for online shopping as financial incentive. Improper users were periodically deleted by managing e-mail addresses to prevent double registration.

We also asked the participants to provide information about their height, weight, previous and present smoking habits, and exercise habits. A body mass index (BMI) of over 25 kg/m^2 was defined as obesity. A previous smoking habit was defined as the experience of smoking 100 cigarettes or more during a 6-month period. A present smoking habit was defined as smoking everyday during the past 1 month. An exercise habit was defined as exercise more than twice a week and of more than 30 min each time for more than the past year. These definitions matched with those of the national annual survey on health and nutrition in 2008 published by Japanese Ministry of Health, Labour and Welfare [13]. Although a BMI of over 30 kg/m^2 is usually considered obese in Western countries, a BMI over 25 kg/m^2 has been defined as obese in the Japanese national annual survey, because Japanese people are less obese than people in Western countries. Therefore, we set 25 kg/m^2 was set as the cut-off for obesity in this study.

In addition to the ODQ, we asked the participants whether they suffered from LBP, which was defined as pain localized between the costal margin and the inferior gluteal folds with or without lower extremity pain in the past 4 weeks, in reference to the past literature [1]. The area was shown diagrammatically on the online questionnaire (Fig. 1); [14]. We asked them to exclude pain associated with menstruation, fever, or cancer in the

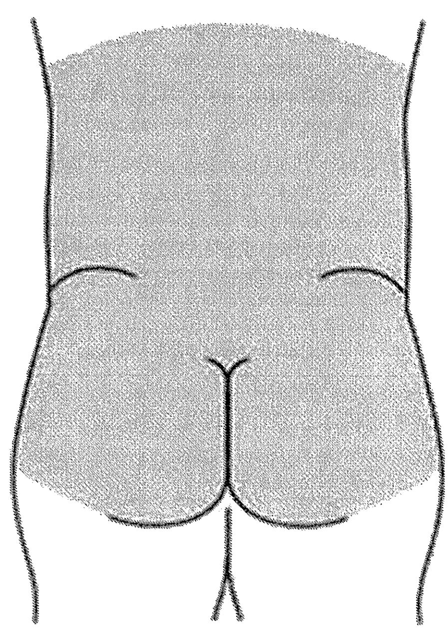


Fig. 1 The optimal definition of lower back pain (LBP) quoted from the past literature [9]. LBP was defined as pain localized between the costal margin and the inferior gluteal folds, which was shown on the diagram

question. We did not ask about the pain intensity, pain duration, or pain pattern. However, we asked participants who had LBP whether the LBP caused disability, with disability being defined as the inability to engage in routine work for more than 1 day caused by the LBP, in reference to a past study by Von Korff [11]. In the main analysis, we classified the participants with LBP into three groups: "LBP with disability", "LBP without disability", and "no LBP". We also asked them whether they suffered from sciatica. We defined sciatica as pain radiating down the leg below the knee. Although this definition may exclude patients with upper lumbar radiculopathy, such as L3, pain radiating down the leg above the knee may include pain derived from diseases of the hip or the pelvis. A recent consensus study on LBP definitions for survey research has suggested that "pain below the knee" is a reasonable proxy for sciatica [14].

First, we estimated the normative score of the ODI after correcting for the age distribution of Japan based on the 2005 population census taken by the Japanese Ministry of Internal Affairs and Communications [15]. In addition, we estimated the ODI of those with or without disability, and evaluated the possible relationship between the ODI score and such factors as sciatica, obesity, and exercise habits. Finally, we estimated the cut-off value of the ODI using the receiver-operating characteristic (ROC) curve by setting the LBP with disability as positive. The area under the curve (AUC), as well as the sensitivity and the specificity, were calculated from the ROC curve.

The statistical analysis was performed using the JMP7.0 software program on a personal computer. $p < 0.05$ was considered to be significant.

This study had the prior approval of the University of Tokyo ethics committee.

Results

The participant's demographic data were similar to those reported by the national survey (Table 1). The prevalence of LBP was 47.5%. One-fourth of the subjects had visited clinics for their LBP. LBP with disability accounted for 12.8% of all participants (Fig. 2).

The average ODI was 8.75 for the 1,200 participants. The ODI by sex and age groups are shown in Table 2. After correcting for the age distribution in Japan, the normative score of the ODI was estimated to be 8.73; 8.80 in males and 8.66 in females. There was a tendency for the ODI to increase gradually with advancing age. Participants in their 70s had the highest score.

The ODI of the LBP without disability group was 11.88. The ODI of the LBP with disability group was 22.07. The ODI of those with disability was the highest in the subjects in their 70s followed by those in their 50s, and it was the lowest in the subjects in their 20s (Fig. 3; Table 3).

Sciatica was reported in 23.6% of the participants who had LBP. In particular, about half of females in their 70s suffered from sciatica. Half of those with sciatica had disability, whereas two-fifths of the LBP with disability group had sciatica. The ODI of those with sciatica was significantly higher than that of those without sciatica (23.07 vs. 12.02; t test, $p < 0.0001$) (Online Resource 1). Females in their 70s had the highest score, and the ODI increased with advancing age.

The ODI of obese subjects was significantly higher than that of non-obese subjects (11.43 vs. 8.14; t test, $p < 0.0001$) (Online Resource 2).

There was no significant difference between the ODI of those who had an exercise habit and those who did not (8.08 vs. 9.04; t test, $p = 0.1399$) (Online Resource 3).

Table 1 Demographic data of the participants

	This study		Japanese national annual survey	
	Mean (SD)	N	Mean (SD)	N
Weight (kg)				
Male	67.3 (11.7)	600	65.8 (11.1)	2,930
Female	52.9 (7.7)	600	52.7 (8.8)	3,567
Height (cm)				
Male	169.5 (6.4)	600	166.9 (7.2)	2,940
Female	157.3 (5.6)	600	153.8 (6.9)	3,592
BMI (kg/m^2)				
Male	23.4 (3.5)	600	23.6 (3.5)	2,930
Female	21.4 (2.9)	600	22.3 (3.6)	3,558
Previous smoking habit (%)	42	1,200	37	7,668
Present smoking habit (%)	19	1,200	24	7,668
Exercise habit (%)	30	1,200	27	4,817

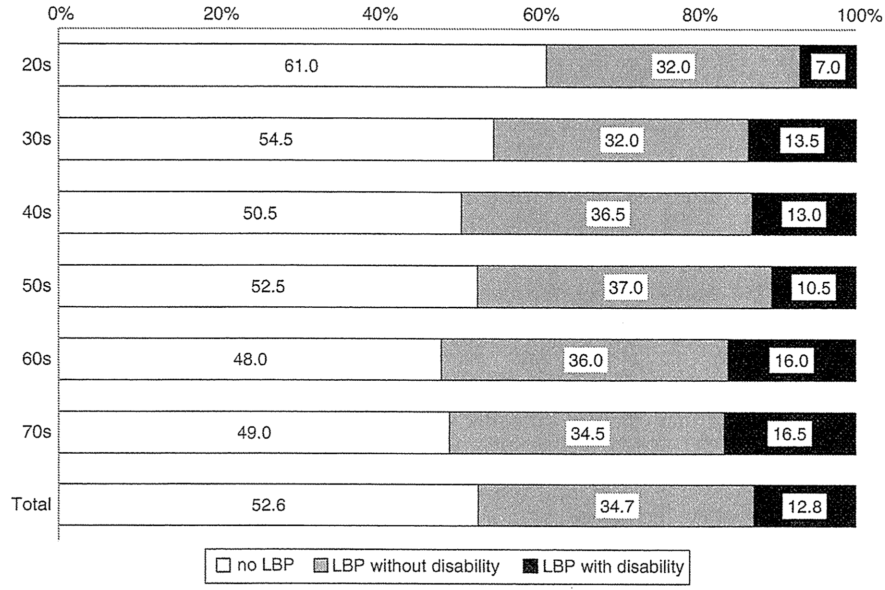


Fig. 2 The proportion of LBP subjects with and without disability

Table 2 Oswestry Disability Index (ODI) by sex and age groups

	N	Mean	95% Confidence interval	Lower quartile	Median	Upper quartile
Male						
20s	100	6.38	4.71–8.05	0	2	8
30s	100	7.42	5.39–9.45	0.5	4	12
40s	100	8.32	6.44–10.20	2	4	12
50s	100	9.52	7.38–11.66	2	5	16
60s	100	10.78	8.45–13.11	2	6	18
70s	100	10.54	8.37–12.71	2	7	18
Total	600	8.83	7.99–9.66	2	4	14
Female						
20s	100	5.04	3.87–6.21	0	2	8
30s	100	6.94	5.42–8.46	2	4	12
40s	100	8.06	6.32–9.80	2	4	12
50s	100	8.58	6.67–10.49	2	5	14
60s	100	9.12	6.88–11.36	2	4	14
70s	100	14.32	11.45–17.19	2	9	23.5
Total	600	8.68	7.85–9.51	2	4	14
Total						
20s	200	5.71	4.69–6.73	0	2	8
30s	200	7.18	5.92–8.44	2	4	12
40s	200	8.19	6.92–9.46	2	4	12
50s	200	9.05	7.63–10.47	2	5	16
60s	200	9.95	8.34–11.56	2	6	16
70s	200	12.43	10.63–14.23	2	8	20
Total	1,200	8.75	8.16–9.34	2	4	14

However in the subjects in their 60s and 70s, the ODI of those with an exercise habit was significantly lower than that of those without (*t* test, $p = 0.0131$ and $p = 0.0034$).

The cut-off value of the ODI which separated LBP with disability from LBP without disability was 12. The AUC of the ROC curve was 0.83, and the sensitivity and the specificity were 76.4 and 75.6%, respectively (Fig. 4).

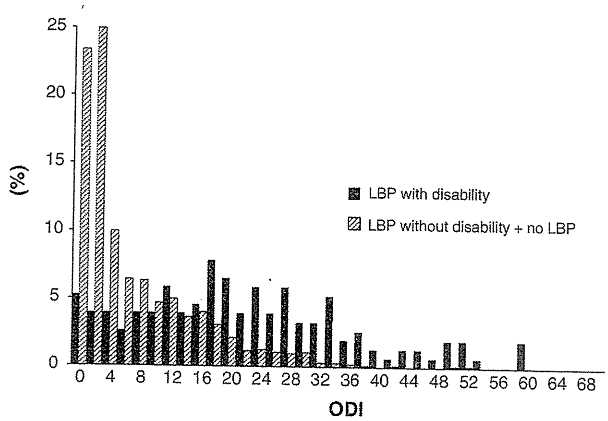


Fig. 3 A histogram of the ODI by LBP with disability. The histogram of the ODI of the group that had LBP with disability is shown by a *black bar*, while that of the group that had LBP without disability or no LBP is shown by the *diagonal bar*. The mean ODI of the LBP with disability group was 22.07

Discussion

The normative score of the ODI in our study was estimated to be 8.73. The similar normative score reported in the review article by Fairbank et al. (10.19) [6] supports the present results. The score of 10.19 in their review was derived from data reported in six publications [16–21], which were performed on subjects from Canada and Finland. Each study showed the normative score of the ODI as a control for its research; however, the population composition of a control varied among these studies. With regard to the adequacy of sampling, we covered the age groups of the participants from their 20s to their 70s, with the expectation of answering properly, because LBP was experienced in all age groups of adults. The ratio of males to females was 1 to 1. The BMI and the rate of exercise in each age group were similar to the results of the national survey, and the rate of previous and present smoking habits was also comparable. Therefore, we think that the backgrounds of the participants were similar to those in the national survey, and that this group was representative of the general Japanese population.

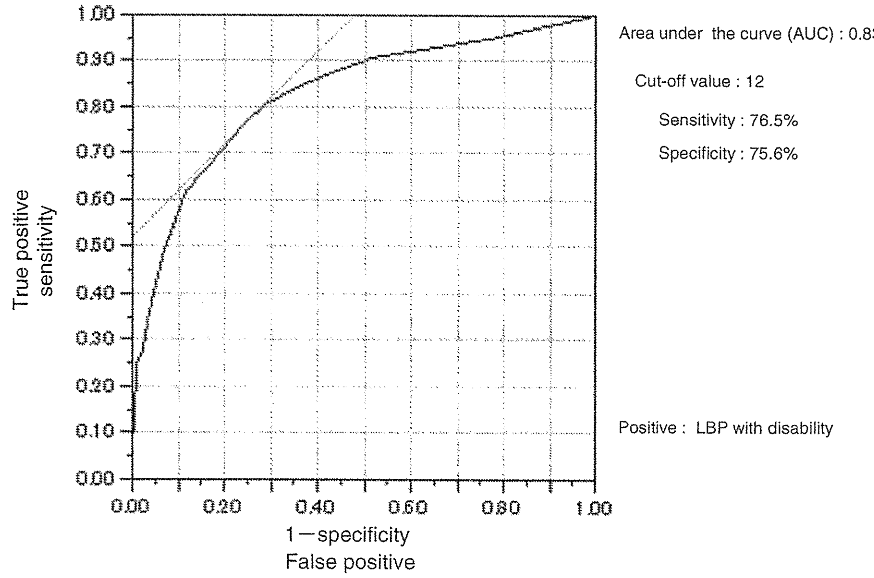
The ODI of the LBP with disability group in our study was 22.07, whereas that of the LBP without disability group was 11.88. Although the mean scores varied based on the definition of disability, we defined disability as the inability to engage in routine work for more than 1 day caused by the LBP, with reference to the past literature [11].

We have found that several factors affected the ODI score. The ODI of those with sciatica was significantly higher than that in those without sciatica. As a recent report showed that the clinical course of those with LBP with referred leg pain was worse than that of patients with LBP alone [22], it may be preferable that those with sciatica and those without sciatica are separately analyzed in outcome studies of LBP. The prevalence of sciatica was 23.6% in this study, while it was previously reported to range from 1.6 to 43% [23]. These differences may indicate that the prevalence may be affected by the definition of sciatica. The diagnosis of sciatica, which was assessed via self-reported questionnaire by participants, may not be accurate, because they are not physicians. Pain radiating below the knee may also include pain derived from osteoarthritis of the knee, especially in aged participants, while this definition may exclude upper lumbar radiculopathy, such as L3. In addition, the ODI of the obese participants whose BMI was over 25 kg/m^2 in this study was significantly higher than that of the normal weight subjects. A systematic review showed that overweight and obese people have a higher prevalence of LBP, where overweight was defined as a BMI of over 25 kg/m^2 and obesity was defined as a BMI of over 30 kg/m^2 [24]. Another difference in the definition between the review and this study was the time when the participants suffered from LBP. It was defined as occurrence in the past year in the review, while we defined it as in the past 4 weeks in this study. However, our results were similar to the past study. Although the relationship between LBP and exercise habits is controversial [25, 26], our results show that those with exercise habits have a lower prevalence of LBP, especially in aged people. With regard to the factors

Table 3 Mean (lower quartile, median, upper quartile) of ODI by disability in the participants who had low back pain (LBP)

	Male		Female		Total	
Disability	+	–	+	–	+	–
20s	21.00 (11, 17, 34)	9.94 (4, 8, 16)	12.00 (1.5, 12, 19.5)	8.58 (4, 8, 14)	15.86 (7.5, 15, 22)	9.28 (4, 8, 14)
30s	16.84 (4, 10, 28)	10.14 (4.5, 11, 16)	20.25 (12, 21, 31.5)	10.50 (4, 11, 16)	17.85 (4, 12, 30)	10.34 (4, 11, 16)
40s	16.67 (8.5, 13, 25.5)	12.97 (6, 12, 20)	17.86 (7.5, 17, 25)	11.00 (4, 10, 16)	17.31 (8, 15, 24.5)	12.00 (5, 12, 16)
50s	25.23 (16, 22, 31)	14.06 (8, 14, 18.5)	27.25 (19.5, 28, 29.5)	11.30 (6, 12, 17.5)	26.00 (18, 26, 30)	12.57 (6, 12, 18)
60s	22.21 (10, 20, 36)	13.44 (6, 10, 20)	22.92 (13, 18, 32)	10.17 (4, 8, 15.5)	22.50 (12.5, 20, 34.5)	11.81 (6, 9, 17.5)
70s	21.83 (12.5, 21, 31.5)	15.17 (8, 14, 24)	33.05 (20, 34, 47)	14.64 (6.5, 10, 22)	28.97 (20, 26, 36)	14.96 (8, 14, 22)
Total	20.47 (9, 20, 29)	12.80 (6, 12, 18)	23.86 (14, 23, 33.5)	10.96 (4, 10, 16)	22.07 (12, 20, 31)	11.88 (6, 10, 16)

Fig. 4 A receiver-operating characteristic (ROC) curve of the ODI in the group that had LBP with disability. The cut-off value was estimated to be 12



associated with the ODI in this study, another study is needed to verify their clinical significance.

We estimated the cut-off value of the ODI on LBP with disability as 12. There has been no previous report of the cut-off value of the ODI, by which we can separate LBP populations into those who have LBP with and without disability. At present, LBP is prevalent in all adult populations, and only a few subjects become disabled. However, these patients are responsible for most of the treatment cost [27]. Efforts at preventing LBP with disability instead of LBP itself are likely to be more effective and efficient. Therefore, we think that estimating a cut-off value which can discriminate people with no or mild LBP without disability from people with disability would be clinically meaningful. Although the cut-off value depends on the definition of disability, this cut-off value can be of great help not only to identify the LBP population who need treatment, but also as a criterion to assess the effects of treatment.

There are some limitations to this study. First, an internet survey may have some bias. One bias is that all the participants in this study had the ability to access and use the internet. They might therefore have been more educated and intelligent than those who did not use the internet, especially in the older age groups. In addition, the participants may therefore not have been members from a lower socioeconomic strata. However, the similarity between the characteristics of the participants and those of the population census in Japan demonstrated that there was adequate sampling. Additionally, some researchers have reported that there is no difference between an internet survey and a paper and pencil survey method, even in older participants [28, 29]. Another potential bias is the sampling-bias that is caused by the number (1,200) used for the sampling. The best design to estimate the normative score may be stratified sampling from the entire Japanese population. However, such a study would be prohibitively time-, labor- and cost-intensive. In the present study, candidates from a representative population of over one million people were chosen by random sampling, and the participants had similar backgrounds as the subjects in the Japanese national survey. Therefore, we think that we were able to obtain equivalent results to the entire population, with a modest cost. Additionally, the estimated normative score of the ODI after correcting for the age distribution in Japan was not substantially different from the average ODI of the 1,200 participants. Therefore, the ODI of the LBP with or without disability, as is shown in Table 3 without correcting for the age distribution, can be considered to be the score for the entire population. Second, the present data was collected from people in Japan who can understand Japanese. Therefore, generalization of the normative score and the cut-off value in this study needs careful consideration, and a further investigation is warranted.

Conflict of interest None.

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Potential risk factors for new-onset of back pain disability in Japanese workers: Findings from the Japan epidemiological research of Occupation-related Back pain (JOB) study

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[Abstract]

Study Design: Two-year, prospective cohort data from the Japan epidemiological research of occupation-related back pain (JOB) study were used for this analysis.

Objective: To examine the association between a new onset of low back pain (LBP) with disability and potential risk factors among initially symptom-free Japanese workers.

Summary of Background Data: Despite strong evidence that psychosocial issues may influence LBP onset among symptom-free persons, these and other LBP risk factors have not been well investigated in the Japanese workplace.

Methods: Of 5,310 participants responding to a self-administered baseline questionnaire (response rate: 86.5%), 3,194 (60.2%) completed both 1-year and 2-year follow-up questionnaires. The baseline questionnaire assessed individual characteristics, ergonomic work demands, and work-related psychosocial factors. The outcome of interest was new-onset LBP with disability during the follow-up period. Incidence was calculated for the participants who reported no LBP during the past year at baseline. Logistic regression was used to explore risk factors associated with new-onset LBP with disability.

Results: Of 836 participants who were symptom-free during the preceding year, 33 (3.9%) reported LBP with disability during the 2-year follow-up. In univariate analyses, "history of LBP", "frequent lifting", "interpersonal stress at workplace", and "monotonous tasks" were all significant predictors of LBP incidence. All of these factors remained statistically significant or almost significant in the multivariate analysis adjusting for the other variables, as well as age and gender: adjusted odds ratio (OR) and 95% confidence interval (95%CI) for history of LBP (OR: 3.25, 95%CI: 1.53-6.91), frequent lifting (OR: 3.77, 95%CI: 1.16-12.3), interpersonal stress at workplace (OR: 2.42, 95%CI: 1.08-5.43), monotonous tasks: (OR: 2.21, 95%CI: 0.99-4.94).

Conclusions: Both ergonomic and work-related psychosocial factors may predict the

development of LBP with disability among previously asymptomatic Japanese workers. Thus, workplace interventions aimed at reducing the incidence of LBP should focus on both ergonomic and psychosocial stress.

Key Words: low back pain;non-specific low back pain;new onset;risk factors;Psychosocial factors;disability;Japanese workers

[Mini Abstract]

The association was examined between new-onset low back pain with disability and potential risk factors among Japanese workers who were initially symptom-free. Results suggest that as well as ergonomic factors, work-related psychosocial factors are significant in the development of future back pain disability in initially symptom-free Japanese workers.

[Key Points]

- The association was examined between a new onset of low back pain (LBP) with disability and potential risk factors among Japanese workers who were initially symptom-free.
- Data from a 2-year, prospective, cohort of the Japan epidemiological research of Occupation-related Back pain (JOB) study were used for this analysis.
- Significant associations were found for "history of LBP", "frequent lifting", "interpersonal stress at workplace", and "monotonous tasks" in univariate analyses and multivariate

analyses adjusting for the other variables, age, and gender.

- Results suggest that as well as ergonomic factors, work-related psychosocial factors are also significant in the development of future back pain disability after more than 1-year symptom-free period among Japanese workers.

[Introduction]

Most adults at some point in their life will experience some degree of low back pain (LBP), most of which (85-90%) is classified as 'non-specific low back pain'.[1,2] As in Western industrialized countries, LBP is one of the most common causes of health disability in Japan, with a reported one-month prevalence of 30.6%.[3] Additionally, LBP is a costly health problem, particularly in the workplace.[4]

Earlier reports suggest that the majority of individuals who have episodes of LBP will experience a recurrence of the problem within a year. [5-8] Thus, previous episodes of LBP can be identified as an important predictor for the occurrence of future episodes.[9-13] In addition to prior LBP, many epidemiological studies have identified other potential risk factors for LBP. In terms of the physical demands of work, tasks such as lifting, bending and twisting, and manual handling are associated with increased risk of back symptoms, pain aggravation, and injuries.[10] In addition to the ergonomic work demands, there is strong evidence suggesting that psychosocial issues may also elevate the risk of LBP onset.[10,11] Unfortunately, given that the cultural and environmental influences on LBP are likely not uniform across all societies,[14] investigations specific to each society are required.

In Japan, the association between the new onset of LBP and potential risk factors including psychosocial factors has not been properly assessed in prospective epidemiological research. In response to this dearth of evidence, we conducted a prospective, cohort study of Japanese workers, entitled the Japan epidemiological research of Occupation-related Back pain (JOB) study. The study collected data on an extensive list of potential risk factors at baseline as well as LBP-related outcomes during 2 years of follow-up. Specifically, the current study focused primarily on LBP with disability, a condition of critical importance to employers and workers. In practice, the prevention of LBP with disability is considered more critical in terms of reducing cost while improving workforce productivity. Indeed, while LBP affects many people, the largest cost to society results from the small proportion of people who become disabled due to LBP.[15]

Using the data from the JOB study, we examined the association between a new onset of LBP with disability and potential risk factors among 1-year symptom-free Japanese workers.

[Materials and Methods]

Data source

Data from a 2-year prospective cohort of the JOB study were used for this analysis. Participants were recruited from 16 workplaces in various occupational fields, located in or near Tokyo. The major occupational groups from these workplaces were office workers, nurses, sales/marketing personnel, and manufacturing engineers. The board of each participating organization was asked to distribute a self-administrated questionnaire, along with a covering letter from the study administration office, to their workers. Respondents were asked to return their completed questionnaire via post, and to provide their name and mailing address for direct correspondence from the study administration office for follow-up purposes. A total of 6,140 baseline questionnaires were distributed. Of these, 5,310 completed questionnaires were returned, yielding a response rate of 86.5%.

The baseline questionnaire included items assessing the severity of LBP and various individual and work-related factors. The respondents were asked to quantify the severity of their LBP into four grades: grade 0 (no LBP), grade 1 (LBP without interfering with work), grade 2 (LBP with interfering with work), and grade 3 (LBP with interfering with work, leading to sick-leave). The grades were determined with reference to Von Korff's grading.[16] LBP was defined as pain localized between the costal margin and the inferior gluteal folds[1], and a diagram of the LBP area was provided within the questionnaire. Additionally, the baseline questionnaire assessed individual characteristics (i.e. gender, age, obesity, smoking habit, and previous episodes of LBP), ergonomic work demands (i.e. frequency of bending, twisting, or lifting at work), and psychosocial factors (i.e. depression, interpersonal stress at work, job control, job satisfaction, and somatization). Psychosocial factors were mainly assessed with the brief job stress questionnaire;[17,18] a self-administered scale, developed by a research working group organized by the Japan Labor Health and Welfare Organization. Question items for the questionnaire were derived from the various standard questionnaires: the Job Content Questionnaire (JCQ)[19] and the National Institute for Occupational Safety and Health (NIOSH)[20] for stress related factors; the Profile of Mood States (POMS)[21] for psychological stress response; the Center for Epidemiologic Studies Depression Scale (CES-D)[22] for depression; the State-trait Anxiety Inventory (STAI)[23] for anxiety; and the Screener for Somatoform Disorders (SSD)[24] and the Subjective Well-being Inventory (SUBI)[25] for somatization. The questionnaire consisted of 57 items and provided standardized scores in 19 work-related stress factors that were scored on a 5-point scale ranging from 1 (lowest) to 5 (highest). The 19 factors include mental workload (quantitative aspect) (3 items), mental workload (qualitative aspect) (3 items), physical workload (1 item), interpersonal stress at work (3 items), work environmental stress (1 item), job control (3 items), utilization of skills and expertise (1 item), job fitness (1 item), job satisfaction (1 item), vigor (3 items), irritability (3 items), fatigue (3 items), anxiety (3 items), depression (6 items), somatic symptoms (11 items), support by supervisors (3 items), support by coworkers (3 items), support by family or friends (3 items), and daily-life satisfaction (2 items). Standardized scores were developed based on a sample of approximately 10,000 Japanese workers. The questionnaire has been demonstrated to have internal consistency, reliability, and criterion validity with respect to the JCQ and NIOSH.[26]

The follow-up questionnaire was distributed at 1 and 2 years after the baseline assessment, and the 2nd questionnaire was only sent to the participants who returned the 1st one. This was because by signing each questionnaire, participants consented to continue participating in the study. Therefore, those who did not return a questionnaire did not consent to participate in the study any longer. Of the 5,310 participants who completed the baseline questionnaire, 3,194 successfully completed and returned both 1-year and 2-year follow-up questionnaires, thereby yielding an overall follow-up rate of 60.2% (3,803 returned the 1st questionnaire, resulting in a follow-up rate of 71.6%). The follow-up questionnaires included questions relating to LBP, such as severity of LBP during the past year, sick-leave because of LBP, medical care seeking, pain duration, and onset pattern. LBP severity was assessed as previously described for the baseline questionnaire.

Ethical approval for the study was provided by the review board of the Japan Labor Health and Welfare Organization. Written informed consent was obtained from all participants prior to study entry.

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, 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/m^2. 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 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