

# The association between lower back pain and health status, work productivity, and health care resource use in Japan

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**Introduction:** This study investigated the effect of pain severity on health status, work productivity, health care resource use, and costs among respondents with lower back pain (LBP), in Japan.

**Materials and methods:** Data from the 2013 Japan National Health and Wellness Survey, a survey of Japanese adults, were analyzed (N=30,000). All respondents provided informed consent, and the protocol was institutional review board-approved. Respondents who reported experiencing LBP were propensity score-matched to those without LBP, based on demographics and health history. Using regression modeling, patients with mild, moderate, and severe pain were compared against matched controls, with respect to health status (Mental and Physical Component Summary scores, and health utilities from the Short Form<sup>®</sup>-36 Health Survey version 2), work productivity (Work Productivity and Activity Impairment – General Health version), health care resource use, and annual per-patient costs (estimated using published annual wages and resource use event costs).

**Results:** A total 1,897 patients reported experiencing LBP in the past month (6.32%); 52.45% reported their pain as mild, 32.79% as moderate, and 14.76% as severe. Increasing pain severity was associated with significantly lower levels of mental component scores (46.99 [mild], 42.93 [moderate], and 40.58 [severe] vs 48.10 [matched controls]), physical component scores (50.29 [mild], 46.74 [moderate], and 43.94 [severe] vs 52.93 [matched controls]), and health utilities (0.72 [mild], 0.66 [moderate], and 0.62 [severe] vs 0.76 [matched controls]) (all  $P < 0.05$ ). Indirect costs were significantly higher ( $P < 0.05$ ) among those with moderate (¥1.69 million [MM] [equivalent to \$17,000, based on United States dollar exchange rates on September 1, 2014]) and severe (¥1.88 MM [\$19,000]) pain, relative to matched controls (¥0.95 MM [\$9,500]). Direct costs were only marginally different ( $P = 0.05$ ) between those with severe pain and matched controls (¥1.33 MM [\$13,000] vs ¥0.54 MM [\$5,000]).

**Conclusion:** Increasing pain severity among respondents with LBP was associated with significantly worse health status, to a clinically-relevant degree, along with greater indirect and direct costs, in Japan.

**Keywords:** low back pain, pain severity, quality of life, cost

## Introduction

According to the Global Burden of Disease study, lower back pain (LBP) is the leading global cause of disability.<sup>1-3</sup> LBP is also among the most common sources of pain,<sup>4</sup> affecting between 12% (point prevalence) and 40% (lifetime prevalence) of the global population, depending upon the time frame assessed.<sup>5</sup> Research in the United States has found that its presence is associated with significant decrements in quality of life and functioning, and increased levels of work-related impairment, health care

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resource-use, and societal costs.<sup>6,7</sup> Indeed, indirect costs for those with chronic LBP in the workforce were reported to be between \$7,000 and \$25,000 per employee per year, depending upon the level of pain severity.<sup>6</sup> A claims analysis by Gore et al estimated direct medical costs of chronic LBP at over \$8,000 per patient per year, more than twice that of matched controls.<sup>8</sup>

Studies in Japan have reported similar findings. Research has suggested that the point prevalence of LBP is between 20% and 25% of the adult population,<sup>9</sup> with approximately half of those who experience LBP reporting it as their primary source of pain.<sup>10</sup> Research has also demonstrated the association between the presence of LBP and patient outcomes. A survey study by Suka and Yoshida administered the EuroQoL-5D (EQ™-5D) to assess quality of life of respondents across five health care centers in Japan.<sup>11</sup> The results suggested a significant burden of LBP as patients with LBP (with and without daily activity impairment) reported significantly worse quality of life than “no pain” controls, for both men and women.<sup>11</sup>

Similarly, a number of studies have shown the effect of LBP on the level of impairment in daily activities. As reported by Suka and Yoshida, 18% of daily activities were impaired because of LBP, after adjusting for age and sex.<sup>10</sup>

Although these studies examined the burden of LBP in Japan, no previous study, to our knowledge, stratified quality of life and economic outcomes by the degree of pain severity, in Japan.

Characterizing the level of LBP severity and its association with patient outcomes can better inform the development and evaluation of future management strategies. As suggested by studies in the West, LBP severity can potentially explain significant variation in patient outcomes.<sup>7,8</sup> The objectives of this study was to further contribute to the literature of the burden of LBP in Japan by examining the cross-sectional association between pain severity and various health outcomes, including health status, work productivity, impairment in daily activities, health care resource use, societal costs, and sleep impairment.

## Methods

### Data source

The data source for this study was the 2013 Japan National Health and Wellness Survey (NHWS) (N=30,000). The NHWS is a self-administered, Internet-based questionnaire distributed to a nationwide sample of adults (aged 18 years or older). Potential respondents for this study were identified through the Lightspeed Research (LSR)

general panel. Panel members explicitly agreed to join the LSR panel and receive periodic invitations to participate in online surveys (not just health-related). Members of the panel were recruited through a variety of means, including coregistration with other Internet panels, e-newsletter campaigns, and banner placements among other channels. The recruitment of panel members is not conducted strictly by convenience – an attempt is made to approximate the distribution of the adult population in the country of interest. For example, in Japan, the sex (52% vs 49% female in the adult population and panel, respectively) and annual income (eg, 32% vs 31% below ¥4 million [MM] in the population and panel, respectively) distributions are nearly identical. Similarly, the regional distribution of the adult Japanese population and of the panel is within 2% of one another, with the exception of Kanto (which comprises 32% of the adult population but 43% of the panel).<sup>12</sup>

Members of the LSR panel were invited to complete the NHWS through a randomly stratified sampling method, to further ensure the final composition of the NHWS sample matched that of the adult Japanese population. Specifically, the International data base of the United States Census was used to calculate the proportion of the population in each age and sex stratum.<sup>13</sup> Members of the LSR panel were recruited in this way to match these characteristics. As reported in an article by Liu et al, even though the stratified sample did not account for other demographic factors, such as income, education, or region, the NHWS sample was generally comparable with the population, with respect to these characteristics.<sup>14</sup> A total of 607,712 invitations were sent (response rate=4.94%). The survey received Institutional Review Board approval (Essex Institutional Review Board, Inc., Lebanon, NJ, USA), and all respondents provided informed consent prior to participating.

## Sample

All respondents of the 2013 Japan NHWS were included in the analysis (N=30,000).

## Measures

### LBP

All respondents were asked whether or not they had experienced pain in the past year. Those who answered affirmatively were then asked whether they had experienced pain in the past month. Those who again answered affirmatively were then presented with a list of different types of pain (eg, LBP, headache, joint, surgery/medical procedure-related, etc). Respondents who reported “lower back pain” as the source

of their pain were considered to have LBP. All others were considered not to have LBP (ie, “controls”). Respondents were not asked to list their primary pain.

### Pain severity

The primary predictor was pain severity, which was measured in the form of a numeric rating scale of pain in the last week (0–10). This continuous measure of pain severity was categorized into mild (scores 0–3), moderate (scores 4–6), or severe (scores 7–10) pain categories. Control respondents (ie, those without LBP) were automatically assigned a category of “none”.

### Demographics

Age (entered continuously), education (coded as university degree vs all else), household income (coded as <¥3 MM; ¥3 MM to <¥5 MM; ¥5 MM to <¥8 MM; ¥8 MM or more; or decline to answer), and health insurance (national health insurance, social insurance, late-stage elderly insurance, other, or no insurance) was assessed for all respondents.

### Health history

Smoking habits (coded as current, former, or never smoker), exercise behavior (the number of days exercised in the past month as reported directly by the respondents), alcohol use (measured by the frequency of alcohol use, from daily to never, though coded as currently consumes alcohol vs abstains), body mass index (BMI) category (coded, based on the World Health Organization recommendation for Asian populations, as: underweight [ $<18.5 \text{ kg/m}^2$ ], acceptable risk [ $18.5$  to  $<23 \text{ kg/m}^2$ ], increased risk [ $23$  to  $<27.5 \text{ kg/m}^2$ ], high risk [ $\geq 27.5 \text{ kg/m}^2$ ], or decline to provide weight),<sup>15</sup> and the Charlson Comorbidity Index (CCI; a measure of comorbidity burden)<sup>16</sup> were also included.

### Sleep difficulties

All respondents in the NHWS were asked: “Thinking of the sleeplessness or difficulty sleeping that you experience, which of the following sleep problems or symptoms do you regularly experience? Please select all that apply”. Respondents then selected the applicable symptoms from a set list. For the purposes of this study, the presence (or absence) of “difficulty falling asleep”, “waking during the night and not being able to get back to sleep”, “waking up several times during the night”, and “poor quality of sleep” were used as outcomes of pain severity as they most closely reflect the insomnia domains of the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V): sleep onset

symptoms, sleep maintenance symptoms, and restorative sleep.<sup>17</sup> Each of these symptoms were examined individually, and a total sleep difficulties variable was also created; all respondents with at least one symptom were assigned to the “sleep difficulties” group, and the remaining respondents were considered not to have sleep difficulties.

### Health outcomes

Health status was assessed using the Physical Component Summary (PCS) and Mental Component Summary scores of the Short Form<sup>®</sup>-36 Health Survey version 2 (SF-36v2<sup>TM</sup>), along with the eight domain scores: Bodily Pain, Physical Functioning, Physical Role Limitations, General Health, Vitality, Social Functioning, Emotional Role Limitations, and Mental Health.<sup>18,19</sup> Health utility scores (SF-6D), derived from the SF-36v2, were also included. Work productivity and impairment was assessed using the Work Productivity and Activity Impairment – General Health (WPAI-GH) questionnaire.<sup>20</sup> Four subscales (absenteeism [the percentage of time missed from work], presenteeism [the percentage of impairment experienced while at work], overall work impairment [the combination of absenteeism and presenteeism], and activity impairment [the percentage of impairment in daily activities]) are generated from the WPAI-GH in the form of percentages, with higher values indicating greater impairment due to the patient’s health. Only respondents currently employed (full-time, part-time, or self-employed) provided data with respect to absenteeism, presenteeism, and overall work impairment. Health care utilization was defined by the number of health care providers seen in the past 6 months, the number of emergency room (ER) visits, and the number of times hospitalized in the past 6 months.

### Cost variables

Indirect and direct costs were estimated from the available NHWS data. Annual indirect costs were calculated by integrating information, from the WPAI-GH, and hourly wage rates, from the Japan Basic Survey on Wage Structure, 2011, using the Lofland method.<sup>21,22</sup> For each employed respondent, his or her annual wage was estimated based on median weekly rates (provided by demographic strata) multiplied by the number of work weeks in a year. Direct costs were estimated by multiplying the number of physician visits and hospitalizations by two (to estimate annual number of visits) and then multiplied by the corresponding unit cost for each, which was obtained from Japan’s Ministry of Health, Labour and Welfare (ER visits were not included in the cost calculations as with the exception of the use of an ambulance,

which was not asked of our respondents, these are associated with trivial independent costs in Japan).<sup>23</sup> In the case of hospitalizations, only a cost per day was obtained from the Ministry of Health, Labour and Welfare, while the NHWS asked respondents for the number of hospitalizations. To align them, we multiplied the cost per day by the average number of days per hospitalization as reported by the Organisation for Economic Cooperation and Development.<sup>24</sup> All costs figures were provided in Japanese yen with a conversion to the United States dollar, based on the exchange rate (¥104 per \$1) as of September 1, 2014.

## Statistical analyses

### Identifying a matched control group

To minimize a sample size imbalance between pain severity groups and controls (ie, those without LBP), which would have overpowered our statistical findings, a propensity score matching process was used to identify a group without LBP that closely resembled those with LBP. To do so, patients with LBP (regardless of severity) were compared with patients without LBP with respect to sociodemographic (as described above) and health history variables (as described above) using chi-square analyses and one-way analysis of variance models. Variables that differed between groups at a level of  $P < 0.25$  were then entered into a logistic regression to predict pain presence (ie, LBP vs no LBP). Propensity score values from this model were saved and then used as the basis for matching each LBP patient with a respondent without LBP whose propensity score value was identical, using a “greedy matching” algorithm.<sup>25</sup> Matched respondents were then considered a “no LBP”-matched control group; respondents who were not matched were removed from further analyses.

Patients with mild, moderate, and severe pain were compared with matched no LBP controls with respect to socio-demographics and health history variables, using chi-square analyses and one-way analysis of variance models. Variables that differed at  $P < 0.25$  were considered covariates and were included in subsequent regression models. This included age, sex, education, annual household income, BMI category, exercise behavior, smoking habits, alcohol consumption, and the CCI. We included these covariates because even though the overall LBP group and the matched control group may not have differed with respect to these variables, there was significant variability across severity. Therefore, to rule out alternative explanations (eg, whether differences in outcomes were due to the CCI as opposed to increasing severity), we

utilized this second-stage regression approach after the propensity score matching.

Pain severity categories (none, mild, moderate, and severe) were then used as the primary nominal predictor of health outcomes, using generalized linear models, holding the identified covariates constant. The “none” category (ie, matched no LBP controls) served as the reference category. Normal distributions with identity link functions were used for predicting health status; negative binomial distributions with log link functions were used for predicting work productivity loss, and health care resource use and costs; and binomial distributions with logit functions were used for predicting the presence of sleep symptoms. Adjusted means for all outcomes were calculated by severity level, using a maximum likelihood algorithm, and were reported on their original metric by level of severity. All analyses were conducted in SAS 9.3.

## Results

A total of  $N=1,898$  respondents reported experiencing LBP (6.33%); 28,102 respondents reported no LBP in the past month and were considered no LBP controls. Of those who reported LBP, 52.48% reported their pain as mild, 32.77% as moderate, and 14.75% as severe. Compared with the no LBP controls (prior to matching), respondents with LBP were significantly older and more likely to be of lower socioeconomic status (ie, lower education and household income) (Table 1) (all  $P < 0.05$ ). With respect to health characteristics, respondents with LBP were significantly more likely to be at high-risk BMI levels, were more likely to have smoked, and had a greater comorbidity burden as measured by the CCI, compared with those without LBP (all  $P < 0.05$ ). Focusing just on those with LBP, increasing severity was associated with an increased probability of being female, lower socioeconomic status, high-risk BMI levels, not exercising, and smoking (all  $P < 0.05$ ).

A matched no LBP control group was identified from those without LBP, using a propensity score matching approach (as described above). Each respondent with LBP was paired with a suitable no LBP respondent, based on their demographic and health history characteristics. One LBP respondent had a sufficiently extreme pattern of demographic and health history characteristics that no suitable control was found. Therefore, the remaining analyses focused on the  $N=1,897$  respondents who reported LBP, and the matched no LBP control group of  $N=1,897$  (Table 2).

**Table 1** Demographic and health characteristic differences among those with LBP and varying pain severity, and those without LBP

	LBP severity				P-value
	No LBP (N=28,102)	Mild (N=996)	Moderate (N=622)	Severe (N=280)	
Age (years)					<0.001
Mean ± SD	47.18±15.45	49.38±13.68	51.35±13.73	50.90±14.01	
Sex, n (%)					<0.001
Female	13,711 (48.79%)	432 (43.37%)	341 (54.82%)	173 (61.79%)	
Male	14,391 (51.21%)	564 (56.63%)	281 (45.18%)	107 (38.21%)	
University education, n (%)					<0.001
Less than university education	14,202 (50.54%)	524 (52.61%)	376 (60.45%)	174 (62.14%)	
University education or higher	13,900 (49.46%)	472 (47.39%)	246 (39.55%)	106 (37.86%)	
Annual household income, n (%)					<0.001
<¥3 MM	5,054 (17.98%)	195 (19.58%)	136 (21.86%)	71 (25.36%)	
¥3 MM to <¥5 MM	6,998 (24.90%)	271 (27.21%)	162 (26.05%)	78 (27.86%)	
¥5 MM to <¥8 MM	7,033 (25.03%)	238 (23.90%)	161 (25.88%)	58 (20.71%)	
¥8 MM or more	5,967 (21.23%)	216 (21.69%)	105 (16.88%)	50 (17.86%)	
Decline to answer	3,050 (10.85%)	76 (7.63%)	58 (9.32%)	23 (8.21%)	
BMI category, n (%)					<0.001
Underweight	3,082 (10.97%)	100 (10.04%)	53 (8.52%)	32 (11.43%)	
Acceptable risk	14,363 (51.11%)	463 (46.49%)	289 (46.46%)	122 (43.57%)	
Increased risk	7,452 (26.52%)	324 (32.53%)	203 (32.64%)	82 (29.29%)	
High risk	1,953 (6.95%)	84 (8.43%)	54 (8.68%)	34 (12.14%)	
Decline to provide weigh	1,252 (4.46%)	25 (2.51%)	23 (3.70%)	10 (3.57%)	
Alcohol use, n (%)					0.087
Do not drink	8,560 (30.46%)	271 (27.21%)	185 (29.74%)	75 (26.79%)	
Drink alcohol	19,542 (69.54%)	725 (72.79%)	437 (70.26%)	205 (73.21%)	
Exercise behavior, n (%)					0.001
Do not exercise	16,296 (57.99%)	534 (53.61%)	370 (59.49%)	185 (66.07%)	
Regularly exercise	11,806 (42.01%)	462 (46.39%)	252 (40.51%)	95 (33.93%)	
Smoking behavior, n (%)					<0.001
Never smoked	16,217 (57.71%)	454 (45.58%)	286 (45.98%)	148 (52.86%)	
Former smoker	6,297 (22.41%)	305 (30.62%)	187 (30.06%)	56 (20.00%)	
Current smoker	5,588 (19.88%)	237 (23.80%)	149 (23.95%)	76 (27.14%)	
Charlson Comorbidity Index					<0.001
Mean ± SD	0.13±0.51	0.27±1.18	0.26±0.61	0.36±0.74	

**Abbreviations:** BMI, body mass index; LBP, lower back pain; SD, standard deviation; MM, million.

The pain characteristics of respondents with LBP are reported in Table 3. Frequency of pain was highly associated with its severity; for example, only 17.59% of patients with mild pain reported daily pain compared with 37.94% of those with moderate pain and 63.21% of those with severe pain ( $P<0.05$ ). Prescription medication use was uncommon overall (only 20% of all LBP respondents used a prescription treatment), whether in isolation or in combination with an over-the-counter treatment), though rates of use increased significantly by severity (from 10.05% to 40.71% in patients with mild to severe pain, respectively) ( $P<0.05$ ). Opioid use was extremely uncommon but also increased by level of severity (0.40% to 2.86%) ( $P<0.05$ ).

Prior to covariate adjustment, levels of health status for respondents with LBP were significantly worse than for

matched no LBP controls and decreased concomitantly with increasing severity (Table 4). Similarly, levels of work impairment, activity impairment, and health care provider visits were also significantly higher than in matched controls and increased along with severity (all  $P<0.05$ ). No significant differences were observed in terms of the number of ER visits or hospitalizations in the past 6 months.

Adjusting for relevant demographic and health history variables, significant decrements in health status were observed for both SF-36v2 summary scores and health utilities when comparing those with varying levels of pain severity and matched no LBP controls (Table 5). Specifically, PCS levels decreased from 48.10 (no LBP) to 46.99 (mild), to 42.93 (moderate), and to 40.58 (severe), and PCS levels decreased from 52.93 (no LBP) to 50.29 (mild), to 46.74 (moderate), and



**Table 2** Demographic and health characteristic differences among those with LBP and varying pain severity, and matched control respondents without LBP

	Pain severity				P-value
	Matched control (N=1,897)	Mild (N=995)	Moderate (N=622)	Severe (N=280)	
Age (years)					0.013
Mean ± SD	51.05±14.73	49.40±13.67	51.35±13.73	50.90±14.01	
Sex, n (%)					<0.001
Female	982 (51.77%)	432 (43.42%)	341 (54.82%)	173 (61.79%)	
Male	915 (48.23%)	563 (56.58%)	281 (45.18%)	107 (38.21%)	
University education, n (%)					<0.001
Less than university education	1,140 (60.09%)	524 (52.66%)	376 (60.45%)	174 (62.14%)	
University education or higher	757 (39.91%)	471 (47.34%)	246 (39.55%)	106 (37.86%)	
Annual household income, n (%)					0.299
<¥3 MM	386 (20.35%)	195 (19.60%)	136 (21.86%)	71 (25.36%)	
¥3 MM to <¥5 MM	516 (27.20%)	271 (27.24%)	162 (26.05%)	78 (27.86%)	
¥5 MM to <¥8 MM	487 (25.67%)	238 (23.92%)	161 (25.88%)	58 (20.71%)	
¥8 MM or more	356 (18.77%)	215 (21.61%)	105 (16.88%)	50 (17.86%)	
Decline to answer	152 (8.01%)	76 (7.64%)	58 (9.32%)	23 (8.21%)	
BMI category, n (%)					0.412
Underweight	210 (11.07%)	100 (10.05%)	53 (8.52%)	32 (11.43%)	
Acceptable risk	897 (47.29%)	463 (46.53%)	289 (46.46%)	122 (43.57%)	
Increased risk	563 (29.68%)	324 (32.56%)	203 (32.64%)	82 (29.29%)	
High risk	168 (8.86%)	83 (8.34%)	54 (8.68%)	34 (12.14%)	
Decline to provide weight	59 (3.11%)	25 (2.51%)	23 (3.70%)	10 (3.57%)	
Alcohol use, n (%)					0.289
Do not drink	574 (30.26%)	271 (27.24%)	185 (29.74%)	75 (26.79%)	
Drink alcohol	1,323 (69.74%)	724 (72.76%)	437 (70.26%)	205 (73.21%)	
Exercise behavior, n (%)					0.002
Do not exercise	1,086 (57.25%)	534 (53.67%)	370 (59.49%)	185 (66.07%)	
Regularly exercise	811 (42.75%)	461 (46.33%)	252 (40.51%)	95 (33.93%)	
Smoking behavior, n (%)					0.021
Never smoked	903 (47.60%)	454 (45.63%)	286 (45.98%)	148 (52.86%)	
Former smoker	572 (30.15%)	305 (30.65%)	187 (30.06%)	56 (20.00%)	
Current smoker	422 (22.25%)	236 (23.72%)	149 (23.95%)	76 (27.14%)	
Charlson Comorbidity Index					0.035
Mean ± SD	0.26±0.65	0.24±0.62	0.26±0.61	0.36±0.74	

**Abbreviations:** BMI, body mass index; LBP, lower back pain; SD, standard deviation; MM, million.

**Table 3** Pain history among those with LBP

	Pain severity			P-value
	Mild (N=995)	Moderate (N=622)	Severe (N=280)	
Frequency of pain, n (%)				<0.001
Daily	175 (17.59%)	236 (37.94%)	177 (63.21%)	
4–6 times a week	100 (10.05%)	105 (16.88%)	41 (14.64%)	
2–3 times a week	218 (21.91%)	144 (23.15%)	29 (10.36%)	
Once a week	123 (12.36%)	40 (6.43%)	12 (4.29%)	
2–3 times a month	205 (20.60%)	63 (10.13%)	13 (4.64%)	
Once a month or less often	174 (17.49%)	34 (5.47%)	8 (2.86%)	
Treatment group, n (%)				<0.001
Rx and OTC	20 (2.01%)	35 (5.63%)	27 (9.64%)	
Rx only	80 (8.04%)	132 (21.22%)	87 (31.07%)	
OTC only	342 (34.37%)	189 (30.39%)	67 (23.93%)	
Untreated	553 (55.58%)	266 (42.77%)	99 (35.36%)	
Use of opioids, n (%)				<0.001
No	991 (99.60%)	612 (98.39%)	272 (97.14%)	
Yes	4 (0.40%)	10 (1.61%)	8 (2.86%)	

**Abbreviations:** LBP, lower back pain; Rx, prescription medication; OTC, over the counter.

**Table 4** Health outcomes differences among those with LBP and varying pain severity, and matched control respondents without LBP

	Pain severity				P-value
	Matched control (N=1,897)	Mild (N=995)	Moderate (N=622)	Severe (N=280)	
Difficulty falling asleep, n (%)	211 (11.12%)	202 (20.30%)	176 (28.30%)	96 (34.29%)	<0.001
Waking up during the night and not being able to go to sleep, n (%)	181 (9.54%)	147 (14.77%)	148 (23.79%)	72 (25.71%)	<0.001
Waking up several times during the night, n (%)	183 (9.65%)	143 (14.37%)	131 (21.06%)	69 (24.64%)	<0.001
Poor quality of sleep, n (%)	182 (9.59%)	222 (22.31%)	180 (28.94%)	94 (33.57%)	<0.001
Total sleep difficulties, n (%)	468 (24.67%)	410 (41.21%)	323 (51.93%)	165 (58.93%)	<0.001
SF-36v2: Mental Component Summary	48.7±9.5	47.3±10.0	43.5±11.0	40.7±11.6	<0.001
SF-36v2: Physical Component Summary	53.43±5.99	51.04±5.38	47.14±6.12	44.01±7.39	<0.001
SF-36v2: Bodily Pain	53.00±8.86	47.08±6.72	41.60±6.62	36.99±7.30	<0.001
SF-36v2: General Health	47.72±9.03	44.79±8.90	40.11±8.81	37.39±9.59	<0.001
SF-36v2: Vitality	51.54±9.50	48.12±9.32	43.58±9.79	39.79±10.20	<0.001
SF-36v2: Social Functioning	51.41±8.50	50.95±8.79	47.38±9.88	44.74±10.75	<0.001
SF-36v2: Mental Health	47.83±10.27	46.84±9.86	42.77±10.93	39.58±11.39	<0.001
SF-36v2: Emotional Role Limitations	51.24±8.61	49.85±8.81	46.37±10.34	43.78±11.61	<0.001
SF-36v2: Physical Role Limitations	53.08±7.35	52.58±6.77	48.81±8.38	45.80±9.79	<0.001
SF-36v2: Physical Functioning	53.98±5.75	54.00±4.74	51.34±6.34	48.89±8.18	<0.001
SF6D: Health state utility score	0.769±0.124	0.728±0.105	0.665±0.107	0.622±0.116	<0.001
Absenteeism %	2.86±12.19	2.07±10.77	3.35±13.07	7.10±18.73	<0.001
Presenteeism %	20.44±24.48	20.12±23.12	35.52±27.44	43.88±28.80	<0.001
Overall work impairment %	22.0±26.5	21.3±24.6	37.2±28.8	45.4±30.6	<0.001
Activity impairment %	22.00±25.39	22.98±24.69	41.14±26.14	53.11±28.23	<0.001
Health care provider visits in past 6 months	4.70±8.75	6.46±14.23	8.40±11.25	11.44±14.13	<0.001
ER visits in the past 6 months	0.09±0.92	0.16±1.85	0.14±1.11	0.21±0.91	0.324
Hospitalizations in the past 6 months	0.50±4.42	0.48±3.78	0.56±3.54	1.06±6.76	0.236

**Note:** Values were expressed as mean ± SD, unless otherwise stated.

**Abbreviations:** ER, emergency room; LBP, lower back pain; SF, Short Form® Health Survey; SF-36v2™, Short Form®-36 Health Survey, version 2; SD, standard deviation.

to 43.94 (severe) (all severity groups significantly lower than matched controls) ( $P<0.05$ ). Respondents with moderate and severe pain also reported significantly worse domain scores than did matched no LBP controls (all  $P<0.05$ ). Although patients with mild pain generally reported significantly lower domain scores as well, no statistically significant differences were observed with respect to Social Functioning, Mental Health, and Physical Functioning domain scores.

Among those employed, moderate and severe pain was associated with significantly higher levels of presenteeism (36.99% and 43.85%, respectively) and overall work impairment (38.48% and 45.13%, respectively) compared with matched no LBP controls (20.48% and 21.98% for presenteeism and overall work impairment, respectively) (all  $P<0.05$ ) (Table 6). No effect of pain severity was observed for absenteeism, and LBP respondents with mild pain did not significantly differ from matched no LBP controls. Levels of impairment in daily activities were significantly higher among those with moderate (42.41%) and severe pain (52.00%) compared with matched no LBP controls (22.15%) (all  $P<0.05$ ); again, no differences were observed between patients with

mild pain and matched no LBP controls. Finally, indirect costs, calculated from observed overall work impairment rates and estimated annual incomes, were significantly higher for those with moderate (¥1.69 MM [approximately \$17,000]) and severe (¥1.88 MM [approximately \$19,000]) pain compared with matched no LBP controls (¥950,243 [approximately \$9,500]) (all  $P<0.05$ ).

With respect to health care resource use visits, the number of physician visits in the past 6 months increased concomitantly with severity, relative to matched controls (4.05 [matched no LBP control], 5.94 [mild], 8.12 [moderate], and 10.16 [severe]) (all groups  $P<0.05$ ). (Table 7). Only patients with severe pain reported significantly more ER visits (0.33 vs 0.10) ( $P<0.05$ ) in the past 6 months and annualized direct costs ( $P<0.05$ ) than did the matched no LBP controls. No differences in the number of hospitalizations in the past 6 months were observed. Similarly, no differences in total direct costs were observed, though those for patients with severe pain were marginally higher than those for patients with no LBP (¥1.33 MM [approximately \$13,000] vs ¥0.54 MM [approximately \$5,000]) ( $P=0.05$ ).

**Table 5** Adjusted means of SF-36v2™ component summary and domain scores by level of pain severity

DV	Pain severity	Adjusted mean	SE	95% LCL	95% UCL	P-value
MCS	Matched control	48.10	0.29	47.52	48.67	–
	Mild	46.99	0.36	46.28	47.69	0.00
	Moderate	42.93	0.43	42.10	43.76	<0.0001
	Severe	40.58	0.60	39.41	41.76	<0.0001
PCS	Matched control	52.93	0.17	52.59	53.27	–
	Mild	50.29	0.22	49.86	50.71	<0.0001
	Moderate	46.74	0.25	46.24	47.24	<0.0001
	Severe	43.94	0.36	43.24	44.64	<0.0001
Bodily Pain	Matched control	52.49	0.24	52.02	52.96	–
	Mild	46.44	0.30	45.86	47.02	<0.0001
	Moderate	41.18	0.35	40.49	41.86	<0.0001
	Severe	36.87	0.49	35.91	37.84	<0.0001
General Health	Matched control	46.80	0.26	46.29	47.32	–
	Mild	43.78	0.33	43.14	44.42	<0.0001
	Moderate	39.23	0.38	38.47	39.98	<0.0001
	Severe	37.14	0.54	36.08	38.20	<0.0001
Vitality	Matched control	50.82	0.28	50.28	51.37	–
	Mild	47.48	0.34	46.81	48.15	<0.0001
	Moderate	42.93	0.40	42.14	43.72	<0.0001
	Severe	39.76	0.57	38.65	40.88	<0.0001
Social Functioning	Matched control	50.99	0.27	50.46	51.52	–
	Mild	50.59	0.33	49.94	51.25	0.25
	Moderate	46.98	0.39	46.20	47.75	<0.0001
	Severe	44.70	0.56	43.62	45.79	<0.0001
Mental Health	Matched control	47.32	0.30	46.73	47.91	–
	Mild	46.60	0.37	45.87	47.33	0.06
	Moderate	42.26	0.44	41.40	43.13	<0.0001
	Severe	39.53	0.62	38.32	40.75	<0.0001
Emotional Role Limitations	Matched control	50.66	0.28	50.11	51.20	–
	Mild	49.21	0.35	48.53	49.88	<0.0001
	Moderate	45.83	0.41	45.03	46.63	<0.0001
	Severe	43.65	0.57	42.52	44.77	<0.0001
Physical Role Limitations	Matched control	52.67	0.23	52.22	53.12	–
	Mild	52.01	0.28	51.46	52.57	0.03
	Moderate	48.46	0.34	47.80	49.12	<0.0001
	Severe	45.80	0.47	44.88	46.73	<0.0001
Physical Functioning	Matched control	53.59	0.17	53.25	53.93	–
	Mild	53.39	0.21	52.97	53.80	0.35
	Moderate	51.04	0.25	50.55	51.53	<0.0001
	Severe	48.86	0.35	48.17	49.55	<0.0001
SF-6D (health utilities)	Matched control	0.76	0.00	0.75	0.77	–
	Mild	0.72	0.00	0.71	0.73	<0.0001
	Moderate	0.66	0.01	0.65	0.67	<0.0001
	Severe	0.62	0.01	0.61	0.64	<0.0001

**Notes:** Generalized linear models, specifying a normal distribution and an identity function, were conducted. All models adjusted for age, sex, education, annual household income, body mass index category, exercise behavior, smoking habits, alcohol consumption, and the Charlson Comorbidity Index.

**Abbreviations:** DV, dependent variable; LCL, 95% lower confidence limit; MCS, mental component summary; PCS, physical component summary; SE, standard error of the mean; SF®, Short Form® Health Survey; UCL, 95% upper confidence limit.

Finally, a significant association between pain severity and sleep difficulties was observed. For each sleep symptom assessed, the adjusted probability of experiencing that symptom increased along with severity. Compared with matched no LBP controls (23%), the adjusted percentage of experiencing any of the assessed symptoms was significantly

higher among those with mild (40%), moderate (51%), and severe (56%) pain (all  $P < 0.05$ ) (Table 8).

## Discussion

Although prior studies in Japan have examined the association between LBP and patient outcomes,<sup>9–11</sup> the stratification



**Table 6** Adjusted means of the probability of employment and work productivity and activity impairment, by level of pain severity

DV	Pain severity	Adjusted mean	SE	95% LCL	95% UCL	P-value
Absenteeism %	Matched control	2.72	0.58	1.79	4.13	–
	Mild	1.64	0.45	0.96	2.81	0.0583
	Moderate	3.10	0.95	1.70	5.67	0.676
	Severe	6.04	2.78	2.45	14.86	0.0827
Presenteeism %	Matched control	20.48	0.99	18.62	22.51	–
	Mild	20.81	1.23	18.54	23.36	0.7772
	Moderate	36.99	2.62	32.19	42.50	<0.0001
	Severe	43.85	4.33	36.14	53.20	<0.0001
Overall work impairment %	Matched control	21.98	1.07	19.97	24.19	–
	Mild	21.88	1.32	19.44	24.62	0.935
	Moderate	38.48	2.77	33.42	44.30	<0.0001
	Severe	45.13	4.57	37.00	55.05	<0.0001
Activity impairment %	Matched control	22.15	0.71	20.80	23.58	–
	Mild	23.67	0.94	21.90	25.58	0.1036
	Moderate	42.41	1.99	38.68	46.49	<0.0001
	Severe	52.00	3.42	45.72	59.14	<0.0001
Indirect costs (¥)	Matched control	950,243	46,836	862,740	1,046,619	–
	Mild	980,778	60,060	869,852	1,105,850	0.5995
	Moderate	1,693,485	124,427	1,466,359	1,955,791	<0.0001
	Severe	1,880,516	195,266	1,534,233	2,304,957	<0.0001

**Notes:** Generalized linear models, specifying a negative binomial distribution and a log link function, were conducted (with the exception of employment, which used a binomial distribution and a logit function, due to its binary nature). All models adjusted for age, sex, education, annual household income, body mass index category, exercise behavior, smoking habits, alcohol consumption, and the Charlson Comorbidity Index.

**Abbreviations:** DV, dependent variable; LCL, 95% lower confidence limit; SE, standard error of the mean; UCL, 95% upper confidence limit.

by severity is a notable advancement. Our results suggest that all forms of LBP are not equal; indeed, the greatest decrement in health status was observed for those with moderate and severe pain, among whom each group had both significant and clinically relevant decrements in health status relative to matched no LBP controls. Although physically debilitating, as would be expected, pain was also associated with

significant and clinically significant decrements in mental health status.

We also found that LBP was associated with an increased probability of experiencing sleep difficulties and that this probability increased along with pain severity. Although not previously reported in Japan, to our knowledge, the relationship between pain and sleep has been observed in other

**Table 7** Adjusted means of health care resource use visits and direct costs in the past 6 months, by level of pain severity

Dependent variable	Pain severity	Adjusted mean	SE	95% LCL	95% UCL	P-value
Physician visits	Matched control	4.05	0.21	3.66	4.48	–
	Mild	5.94	0.37	5.26	6.72	<0.0001
	Moderate	8.12	0.59	7.04	9.38	<0.0001
	Severe	10.16	1.05	8.31	12.44	<0.0001
ER visits	Matched control	0.10	0.02	0.06	0.16	–
	Mild	0.16	0.05	0.09	0.29	0.1495
	Moderate	0.14	0.05	0.07	0.29	0.3215
	Severe	0.33	0.17	0.12	0.92	0.0202
Hospitalizations	Matched control	0.37	0.09	0.23	0.61	–
	Mild	0.45	0.15	0.24	0.85	0.6016
	Moderate	0.47	0.17	0.23	0.96	0.5461
	Severe	0.92	0.49	0.32	2.64	0.0964
Direct costs (¥)	Matched control	544,075	114,886	359,683	822,996	–
	Mild	659,684	183,111	382,883	1,136,598	0.5010
	Moderate	744,163	231,294	404,674	1,368,457	0.3289
	Severe	1,332,143	613,351	540,303	3,284,465	0.0535

**Notes:** Generalized linear models, specifying a negative binomial distribution and a log link function, were conducted. All models adjusted for age, sex, education, annual household income, body mass index category, exercise behavior, smoking habits, alcohol consumption, and the Charlson Comorbidity Index.

**Abbreviations:** ER, emergency room; LCL, 95% lower confidence limit; SE, standard error of the mean; UCL, 95% upper confidence limit.

**Table 8** Adjusted probabilities of having sleep difficulties, by level of pain severity

DV	Pain severity	Adjusted probability	SE	95% LCL	95% UCL	P-value
Difficulty falling asleep	Matched control	0.10	0.01	0.09	0.12	–
	Mild	0.19	0.02	0.16	0.23	<0.0001
	Moderate	0.27	0.02	0.23	0.32	<0.0001
	Severe	0.30	0.03	0.25	0.37	<0.0001
Waking up during the night and not being able to go back to sleep	Matched control	0.09	0.01	0.07	0.10	–
	Mild	0.14	0.01	0.11	0.17	<0.0001
	Moderate	0.22	0.02	0.19	0.26	<0.0001
	Severe	0.23	0.03	0.18	0.28	<0.0001
Waking up several times during the night	Matched control	0.09	0.01	0.07	0.11	–
	Mild	0.14	0.01	0.11	0.16	<0.0001
	Moderate	0.20	0.02	0.16	0.24	<0.0001
	Severe	0.22	0.03	0.17	0.28	<0.0001
Poor sleep quality	Matched control	0.09	0.01	0.07	0.10	–
	Mild	0.21	0.02	0.18	0.24	<0.0001
	Moderate	0.28	0.02	0.24	0.33	<0.0001
	Severe	0.31	0.03	0.25	0.37	<0.0001
Sleep difficulties (presence of any of the above four difficulties)	Matched control	0.23	0.01	0.21	0.26	–
	Mild	0.40	0.02	0.36	0.44	<0.0001
	Moderate	0.51	0.02	0.46	0.56	<0.0001
	Severe	0.56	0.03	0.50	0.62	<0.0001

**Notes:** A generalized linear model, specifying a binomial distribution and a logit function, was conducted. The model adjusted for age, sex, education, annual household income, body mass index category, exercise behavior, smoking habits, alcohol consumption, and the Charlson Comorbidity Index.

**Abbreviations:** DV, dependent variable; LCL, 95% lower confidence limit; SE, standard error of the mean; UCL, 95% upper confidence limit.

studies in the United States and Europe.<sup>8,26–28</sup> These results reinforce the broader effect pain has on the patient.

LBP was not significantly associated with greater rates of absenteeism, but moderate-to-severe pain was associated with greater rates of presenteeism and subsequently, overall work impairment and indirect costs. These findings are consistent with those observed in the West, where it has been found that pain tended to disproportionately affect presenteeism more than absenteeism.<sup>6</sup> Mild pain was comparable with matched no LBP controls, in terms of work impairment and indirect costs.

Increasing severity was associated with an increased number of physician visits, though no differences (with the exception of the comparison between patients with severe pain and matched no LBP controls, in terms of ER visits) were observed on other health care resource utilization events. Only patients with severe pain had marginally higher estimated direct costs than did matched no LBP controls. This is a weaker pattern than that observed in the United States,<sup>7</sup> although beyond fundamental cultural and health care system differences, there were also differences in method (eg, claims analysis vs patient-reported) that may account for the discrepancy.

Overall, the stratification by severity in the current study provides a useful extension of the literature. These

results suggest that the severity of LBP pain may dictate the manifestation of its effects. For example, patients presenting with mild pain may have an impact on their quality of life, but the effects on their ability to work may be less perceptible. In contrast, patients presenting with moderate-to-severe are likely to have effects on both their quality of life and work productivity. Additionally, from a patient-outcomes perspective, there appears to be substantially more to gain by alleviating the pain experienced for those in the moderate-to-severe category.

Another implication of this study is a call for improved management among patients with LBP in Japan. Despite the severity and frequency of pain reported by patients, and the poor outcomes observed, the majority of patients were not being prescribed a treatment for their pain. As this study was not intended to assess treatment effectiveness or reasons for lack of treatment, more studies are needed to better understand the lack of sufficient management of pain in Japan and to potentially address this through, among other things, additional education for patients.

## Limitations

Although the NHWS was not designed to assess the prevalence of LBP, the prevalence of LBP in our study was noticeably lower than that reported in the literature (10%–20% or more,

vs 6% in our study).<sup>5,9</sup> We attribute this largely to method differences. Due to the Internet survey method, patients with debilitating LBP were likely underrepresented as the severity of their condition might have prevented them from being able to join an Internet panel and complete survey studies. Also, the NHWS uses a series of questions to assess LBP (“Have you experienced pain in the past 12 months?”, “Have you experienced pain in the past month?”, “What type of pain?” with approximately 20 possible selections). It is possible we ended up excluding more patients by asking several incrementally leading questions prior to asking about LBP, compared with other surveys that asked about LBP directly.

This study was entirely patient-reported, and no confirmation of diagnosis, treatment usage, or health care resource utilization was available. This study also focused exclusively on LBP only, and relevant subgroups (such as chronic LBP) could not be examined due to lack of sufficient sample size. The NHWS is cross-sectional, and therefore a causal relationship between pain severity and health outcomes cannot be established. Related to this point, we identified as many confounding variables as possible, but other variables not assessed may have contributed. The cross-sectional nature of the survey also prevented us from fully exploring potential mediating relationships. For example, it is possible that LBP could have contributed to a lack of exercise and an increased BMI (among other things), which in turn could have affected health outcomes. By controlling for these factors (as we did), we may have underestimated the effect of LBP since we ignored these indirect pathways. This should be further explored in future studies. Our analytical approach also assumed independence between LBP and matched controls; the significance testing would have been affected (ie, more liberal) had we chosen to assume these groups were dependent.

It also should be noted that there are many dimensions to the experience of pain (eg, frequency and intensity). We asked patients directly to report their severity, but it was unclear which specific dimensions of pain led to their responses. As a final limitation, the NHWS is broadly representative of the adult Japanese population with respect to key demographic characteristics; however, there may be other differences (eg, comorbidity profile, health care attitudes, etc) that may limit the generalizability of the findings. For example, those without Internet access and disenfranchised groups would be underrepresented.

## Conclusion

Worldwide, LBP represents one of the most common and one of the most debilitating forms of pain. Although studies

from Japan have found an effect of LBP on health outcomes, no previous study, to our knowledge, stratified the various outcomes by the level of pain severity. Our results suggest an increasing burden on the patient and society as severity increases, particularly for moderate-to-severe pain.

## Disclosure

The data source for this study, the National Health and Wellness Survey (NHWS), was a survey conducted by Kantar Health. Pfizer, Inc. purchased access to the NHWS data and funded the analysis and preparation of this manuscript. Kantar Health acted as a paid consultant group to Pfizer in connection with the development of this manuscript.

Dr DiBonaventura is an employee of Kantar Health. Drs Sadosky, Cappelleri, and Fujii, and Ms Ebata were employed by Pfizer Inc. at the time of the study. The authors report no other conflicts of interest.

No off-label or investigational use is discussed in this paper.

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