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V. 研究成果の刊行物・別刷

The effect of guidance for home exercise and activities of daily living on female adolescents experiencing adverse events after human papillomavirus vaccination in Japanese multidisciplinary pain centres

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T Ushida, M Shibata, M Kitahara, et al. The effect of guidance for home exercise and activities of daily living on female adolescents experiencing adverse events after human papillomavirus vaccination in Japanese multidisciplinary pain centres. *Pain Res Manag* 2015 In Press.

BACKGROUND: Two prophylactic human papillomavirus (HPV) vaccines (quadrivalent and bivalent) were made available for primary prevention of cervical cancer. Local and systemic injection-related symptoms were generally mild, and serious adverse events (AEs) were rare. More than 230 women in Japan experienced severe AEs, such as persistent pain and headache, after vaccination; therefore, Japan stopped recommending the HPV vaccines. The authors' research group began treating female adolescents experiencing AEs following HPV vaccination.

OBJECTIVE: To survey the characteristics and effects of cognitive behavioral therapy on female adolescents experiencing AEs following HPV vaccination in Japanese multidisciplinary pain centres.

METHODS: One hundred forty-five patients experiencing AEs after HPV vaccination were reviewed retrospectively, and 105 patients were provided guidance for home exercise and activities of daily living, based partially on a cognitive-behavioral approach. Pain intensity was rated by the patients using a numerical rating scale. Furthermore, the Hospital Anxiety and Depression Scale was used to determine levels of anxiety and depression, and the Pain Catastrophizing Scale was used to determine levels of physical and emotional distress associated with their pain.

RESULTS: Eighty of the 105 patients who received guidance were followed-up; 10 showed a marked improvement and 43 demonstrated some improvement.

CONCLUSIONS: Guidance for home exercise and activities of daily living based on a cognitive-behavioral approach alleviated, to some extent, the AEs that women in Japan experienced following HPV vaccination.

Key Words: Cognitive-behavioural approach; Human papillomavirus; Side effects; Vaccines

L'effet de conseils de faire de l'exercice à domicile et de poursuivre les activités de la vie quotidienne chez des adolescentes souffrant d'effets indésirables après un vaccin contre le virus du papillome humain dans des centres multidisciplinaires japonais de la douleur

HISTORIQUE : Deux vaccins prophylactiques contre le virus du papillome humain (VPH, quadrivalent et bivalent) sont homologués pour la prévention primaire du cancer du col de l'utérus. Les symptômes locaux et systémiques liés à l'injection sont généralement légers, et les graves effets indésirables (EI), rares. Toutefois, la vaccination a suscité de graves EI, tels qu'une douleur persistante et des céphalées, chez plus de 230 femmes japonaises. Le Japon a donc cessé de recommander les vaccins contre le VPH. Le groupe de recherche des auteurs a commencé à traiter les adolescentes qui avaient souffert d'EI après le vaccin contre le VPH.

OBJECTIF : Sonder les caractéristiques et les effets d'un traitement cognitivo-comportemental chez des adolescentes qui ressentent des EI après un vaccin contre le VPH dans des centres multidisciplinaires japonais de la douleur.

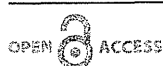
MÉTHODOLOGIE : Les chercheurs ont fait l'analyse rétrospective de 145 patientes qui ont ressenti des EI après le vaccin contre le VPH, et 105 ont reçu le conseil de faire de l'exercice à domicile et de poursuivre les activités de la vie quotidienne, partiellement en fonction d'une démarche cognitivo-comportementale. Ils ont classé l'intensité de la douleur selon les patientes au moyen d'une échelle de classement numérique. Ils ont également utilisé l'échelle d'anxiété et de dépression en milieu hospitalier pour déterminer les taux d'anxiété et de dépression, de même que l'échelle de catastrophisation de la douleur pour déterminer les taux de détresse physique et affective associés à leur douleur.

RÉSULTATS : Quatre-vingts des 105 patientes qui ont reçu des conseils ont fait l'objet d'un suivi. Dix ont révélé une amélioration marquée et 43, une certaine amélioration.

CONCLUSIONS : Le conseil de faire de l'exercice à domicile et de poursuivre les activités de la vie quotidienne selon une démarche cognitivo-comportementale a soulagé, dans une certaine mesure, les femmes japonaises qui ressentaient des EI après un vaccin contre le VPH.

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Cervical cancer is the fourth most common cancer affecting women in the world (1). Genital infection with human papillomavirus (HPV) types 16 and 18 can cause cervical cancer (2). Two prophylactic HPV vaccines (quadrivalent and bivalent) have been available for primary prevention of cervical cancer in >100 countries. The safety of both vaccines was evaluated (2,3). Local and systemic injection-related symptoms were generally mild and serious adverse events (AE) were rare. The most common local AEs included pain, swelling and erythema at the injection site. The most common systemic AEs included vasovagal syncope, dizziness, nausea and headache. The event rate of these symptoms was <0.1%.

Both vaccines were introduced in Japan in 2010 and, as of April 2013, Japanese women were required to receive one of these vaccines. The introduction of the vaccines generated controversy over their safety (4). In Japan, 8.75 million doses were administered. Mass media reported that >230 women experienced severe AEs, such as persistent pain and headache, after vaccination. The Vaccine Adverse Event Reporting System in the United States received reports of 25,176 AEs following HPV vaccination; the rate of serious AEs was two to three reports per 100,000 doses (2,5). Although the rate of serious AEs in Japan was the same as that reported from the United States, several doctors, the social community including the patients and their family members, and mass media challenged the recommendation. Japan could no longer ignore the protests, which resulted in the country no longer recommending the HPV vaccines. In Japan, some researchers regard the symptoms as a consequence of psychosomatic reactions, while others propose plausible alternative mechanisms. The Ministry of Health, Labour and Welfare asked us to organize a research group to treat women experiencing AEs following HPV vaccination. In July 2013, our research group began treating female adolescents experiencing AEs. In almost all cases, there was no clinical or laboratory evidence of relevant pathology for their symptoms, which included headache and musculoskeletal pain, despite persistent complaints.

Chronic pain in adolescents interferes with their daily lives, and is associated with functional disability and distress (6,7). In these cases, satisfactory treatment outcomes may be unachievable using a uniform therapeutic approach seeking only to eliminate pain. Often a multifaceted, comprehensive approach is needed. In particular, therapeutic approaches based on cognitive behavioral therapy (CBT) under multiple academic disciplines are recommended (6-9). Pain and function improve in youth receiving CBT for chronic pain (6,7). CBT consists of behavioral strategies for engagement with normal daily activities, a focus on the self-regulation of emotions and the use of techniques for reducing aversive arousal. Therefore, we decided to consider these women as common patients experiencing chronic pain, and treated them by providing guidance for home exercise and activities of daily living (ADL), based partially on a cognitive-behavioral approach under multiple academic disciplines. In the present article, we report the characteristics and effects of CBT on female adolescents experiencing AEs after HPV vaccination in Japanese multidisciplinary pain centres.

METHODS

Samples and informed consent

A retrospective analysis from July 2013 to July 2014, including women who visited multidisciplinary pain centres in Japan was conducted. All patients were referred from other hospitals to the pain centres because of AEs following HPV vaccination. Treatment protocols used in the present study were based on institutional policy and clinical guidelines approved by the institutional review board of each institution. After obtaining approval from the institutional review board (reference number for Aichi Medical University [Nagakute, Japan]: 12-067), it was explained to all patients that demographics, symptoms, course of pain and medical records would be recorded and stored for all patients for future possible use in the author's research. Written informed consent was provided from each patient on their initial visit to the pain centres.

TABLE 1
Patient characteristics

Characteristic	Accept	Decline	P
Age, years	15 (12–19)	16 (12–19)	0.0786
Vaccine, n (%)			0.1443
Quadrivalent	33 (31.4)	9 (25.0)	
Bivalent	69 (65.7)	27 (65.0)	
Unknown	3 (2.8)	4 (10.0)	
Vaccine doses, n (%)			0.9366
3 doses	77 (73.3)	31 (77.5)	
2 doses	17 (16.2)	5 (12.5)	
1 dose	9 (8.6)	3 (7.5)	
Unknown	2 (1.9)	1 (2.5)	
Onset			0.5483
After first vaccination, n (%)	9 (8.6)	2 (5.0)	
Onset interval, days	0 (0–21)	10 (9–11)	
After second vaccination, n (%)	13 (12.4)	7 (17.5)	
Onset interval, days	1 (0–90)	9 (0–90)	
After third vaccination, n (%)	65 (61.9)	22 (55.0)	
Onset interval, days	30(0–1230)	105 (1–690)	
Duration of symptom, months	12 (1–48)	18 (2–37)	0.2839
Pretreatment HADS			
Anxiety	5 (0–17)	6 (0–15)	0.2140
Depression	4 (0–16)	5 (0–16)	0.2409
Pretreatment PCS	27.5 (0–51)	30 (0–52)	0.8238
Pretreatment NRS of pain	5 (0–10)	4 (0–7)	0.0207

Data presented as median (range) unless otherwise indicated. HADS Hospital Anxiety and Depression Scale; NRS Numerical rating scale; PCS Pain Catastrophizing Scale

TABLE 2
Accept group patient symptoms (n=105)

Symptom	Age, years							
	12	13	14	15	16	17	18	19
Headache	2	0	3	7	1	2	2	0
Myalgia	0	5	7	3	3	2	3	1
Arthralgia	0	4	7	2	2	2	0	2
Dizziness	0	0	1	0	0	1	1	0
>1 symptom	1	6	14	8	7	5	0	1

Data presented as n. P=0.1807

Procedures

Interview: Patients' clinical and laboratory data, which was provided by the patient, were reviewed. Additional medical examinations were sometimes performed if the data provided was insufficient. Based on their symptoms, signs, physical condition and medical data, it was confirmed and explained to these women that in almost all cases there was no clinical or laboratory evidence of relevant pathology in their pain and its associated symptoms. Some patients and family members declined to accept this (decline group) (n=40). Three-quarters of the women who presented (n=105) accepted this (accept group), to whom the provision of guidance for home exercise and ADL based partially on a cognitive-behavioral approach was proposed.

Measures: At the initial visit, data were collected from all patients using standardized self-reported measures, which included demographic, symptom, and history and duration of pain information. Pain intensity was rated by patients using a numerical rating scale (NRS), in which 0 indicated no pain and 10 the greatest pain possible. Furthermore, the Hospital Anxiety and Depression Scale (HADS) was

TABLE 3
Accept group treatment outcomes

Outcome	Age, years							
	12	13	14	15	16	17	18	19
Marked improvement	1	2	4	1	1	0	1	0
Some improvement	0	8	12	7	6	5	3	2
No improvement	1	3	7	6	4	3	1	0
Deterioration	0	0	0	0	2	0	0	0

Data presented as n. $P=0.5521$

TABLE 4
Accept group treatment outcome per symptom

Outcome	Symptom				>1 symptom
	Headache	Myalgia	Arthralgia	Dizziness	
Marked improvement	4	1	1	0	4
Some improvement	7	7	11	2	16
No improvement	3	7	3	1	9
Deterioration	1	0	0	0	1

Data presented as n. $P=0.6826$

used to determine levels of anxiety and depression, and the Pain Catastrophizing Scale (PCS) was used to determine the levels of physical and emotional distress associated with the current pain problems that the patient and their family members associated with their HPV vaccination. HADS consists of 14 items; the anxiety and depression subscales each included 7 items (9-11). A 4-point response scale (from 0 representing absence of symptoms, to 3 representing maximum symptoms) was used, with possible scores for each subscale ranging from 0 to 21. The PCS is a 13-item scale that assesses three types of negative thinking styles related to pain (11-13). Subjects were asked to reflect on past painful experiences and indicate on a 5-point scale ranging from 0 ('not at all') to 4 ('always') the degree to which they experienced each of the 13 thoughts or feelings when experiencing pain.

Treatments: Patients and their family members were provided with the following explanation: prolonged pain can result in sleep disorders, decreased desire, anxiety, depression and decreased routine activity, occasionally causing withdrawal from school or society, and otherwise disrupting daily activities (6,7,9,14). As a result, patients with chronic pain fall into a vicious cycle in which these psychological and social factors complicate their condition (6-9). In such cases, therapeutic approaches based on CBT under multiple academic disciplines are recommended. CBT enables patients to deepen their understanding of their pain, and teaches self-control and coping strategies to encourage behavioural modifications that allow them to better confront their pain, and also maintain and improve ADL (6-9,14,15).

Furthermore, guidance was designed to inform the patients and their family members about how to correct or eliminate excessive fear of pain, improper thinking for treating pain and anxiety caused by distorted cognition, as well as how to control activity levels by appropriate pacing according to a doctor (anesthesiologist or orthopedic surgeon) for engagement with normal daily activities; the patients and their family members were asked to practice these techniques at home. At each visit, guidance was arranged according to the patients' daily activities. Frequency of visits ranged from once per month to once every two months. In regard to stretching, a doctor (orthopedic surgeon) or physiotherapist instructed the patients about how to stretch the muscle groups in their shoulder girdles, lumbar area, hips, thighs and lower legs; instruction was tailored to each patient. Stretching consisted of self-performed static stretching, with each muscle group extended for 20 s twice per day. Also, patients were provided with instructions for muscular strengthening exercises, to strengthen the trunk and leg muscle groups in the supine, sitting and standing

TABLE 5
Treatment outcomes and duration of symptom for HADS and PCS in the accept group

	Duration of symptom, months	HADS		
		Anxiety	Depression	PCS
Marked improvement	11 (1-31)	5 (1-9)	5 (0-13)	27 (18-36)
Some improvement	9.5 (1-40)	4 (0-11)	3 (0-14)	30 (6-42)
No improvement	9 (1-49)	5 (0-15)	5 (0-15)	27 (0-45)
Deterioration	8.5 (5-12)	3.5 (1-6)	5.5 (4-7)	24 (12-36)
P*	0.1139	0.4978	0.4098	0.9650

Data presented as median (range) unless otherwise indicated. *P value calculated using the Kruskal-Wallis test. HADS Hospital Anxiety and Depression Scale; PCS Pain Catastrophizing Scale

positions; patients were instructed to perform 10 repetitions twice per day under their own body weight, but this could be modified for each patient. In nine cases, psychotherapists provided the patients and their family members with counselling as needed.

Data analysis

Patients were categorized as showing marked signs of improvement ($\geq 60\%$ improvement in NRS for pain compared with initial visit), some improvement ($>20\%$ to 60% improvement in NRS compared with initial visit), no improvement (0% to $<20\%$ improvement in NRS compared with initial visit) or deterioration ($<0\%$ improvement in NRS compared with initial visit), depending on the state of pain six months after the initial visit. In addition, patients who did not visit the hospital again with an appointment for a follow-up visit and those who visited the pain centres to receive a second opinion were categorized separately.

RESULTS

Characteristics of the patients are described in Table 1. There was no significant difference between the accept and decline groups in the type of vaccine administered ($P=0.1443$ [χ^2 test]). In addition, there was no significant difference between the two groups in the vaccine dose ($P=0.9366$ [χ^2 test]). There was no statistically significant difference between the two groups in the median duration of symptoms ($P=0.2839$ [Mann-Whitney test]). The median (range) of the anxiety subscale of HADS before treatment was 5 (0 to 17) in the accept group and 6 (0 to 15) in the decline group ($P=0.2140$ [Mann-Whitney test]). The median of the depression subscale of HADS before treatment was 4 (0 to 16) in the accept group and 5 (0 to 16) in the decline group ($P=0.2409$ [Mann-Whitney test]). The median of the PCS before treatment was 27.5 (0 to 51) in the accept group and 30 (0 to 52) in the decline group ($P=0.8238$ [Mann-Whitney test]). The NRS demonstrated a statistically significant difference; however, the difference was not clinically significant.

Table 2 summarized the distribution of symptoms in the accept group for each age. There were no significant differences in the distribution of symptoms in association with the age of the subjects ($P=0.1807$ [χ^2 test]). Pain improvement in the accept group is described for each age in Table 3. There were no significant differences in the distribution of the improvement in association to the age of the patient ($P=0.5521$ [χ^2 test]). There were no significant differences in treatment outcomes for each different type of symptom ($P=0.6826$ [χ^2 test]) (Table 4). There were no significant differences of duration of symptoms, and the HADS and PCS scores between the treatment outcomes before treatment (Table 5).

DISCUSSION

Two prophylactic HPV vaccines (quadrivalent and bivalent) were introduced in Japan. The cause of serious symptoms among female adolescents vaccinated with the HPV vaccines and the safety of the vaccines has yet to be verified. In the present study, we confirmed and

explained to our patients that in almost all cases there was no clinical or laboratory evidence of relevant pathology for their pain and its associated symptoms, based on their symptoms, signs, physical condition and medical data. While some patients and family members declined to accept this (n=40), three-quarters of the women who presented (n=105) accepted this. In Japan, some researchers regard the symptoms as a consequence of psychosomatic reactions, so we had expected that psychological issues of the decline group may have been worse than those of the accept group. Although we compared the background between these two groups, we did not identify any significant differences in the type and dose of vaccine, or the duration of symptoms and psychological issues according to HADS and PCS. However, we believe that further studies addressing these points are required. NRS revealed a statistically significant difference; however, we concluded that the difference was not clinically significant.

Given that in almost all cases there was no clinical or laboratory evidence of relevant pathology for the patients' pain, we handled these patients as common patients experiencing chronic pain, and provided them with guidance for home exercise and activities of daily living, based on a cognitive-behavioral approach under multiple academic disciplines (6-9). As revealed in the present study, this type of approach improved the symptoms in 66.7% of 80 patients who were followed up. Although we believed that some of the symptoms experienced by participants may have been influenced by the stage of their mental and physical development, and endocrine factors that change while girls develop, our results did not reveal that type of influence. In addition, we found most treatment responders displayed moderate rather than marked improvement. We also analyzed types of symptoms associated with the treatment outcomes, and we did not observe any significant differences; however, patients with myalgia were less likely to experience pain reduction. Therefore, we postulate that these individuals easily experience somatization and it may be difficult for them to realize improvement of their symptoms. Moreover, we analyzed psychological issues associated with treatment outcomes, and we did not observe any significant differences. However, further studies are required in this area.

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There were several limitations to the present study. First, the present report describes a retrospective case series and not a randomized control analysis; however, AEs after HPV vaccination have been the subject of public concern. Therefore, we believed that we should not treat patients experiencing AEs using randomized control research techniques in the pain centres. We did not focus on the cause of serious symptoms among female adolescents vaccinated with the HPV vaccines and their safety in the present case series. We, therefore, need further research comparing women who experienced AEs with women who did not, to ascertain the cause of serious symptoms after HPV vaccination and their safety. Also, it would be helpful to clarify what components of treatment are associated with symptom improvement, and whether different symptoms demonstrate better improvement with specific treatment components.

In conclusion, guidance for home exercise and ADL based on a cognitive-behavioural approach alleviated, to some extent, the AEs that women experienced after HPV vaccination in Japan.

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Predictive factors for the outcome of multidisciplinary treatments in chronic low back pain at the first multidisciplinary pain center of Japan

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Abstract. [Purpose] Multidisciplinary treatments are recommended for treatment of chronic low back pain. The aim of this study was to show the associations among multidisciplinary treatment outcomes, pretreatment psychological factors, self-reported pain levels, and history of pain in chronic low back pain patients. [Subjects and Methods] A total of 221 chronic low back pain patients were chosen for the study. The pretreatment scores for the 10-cm Visual Analogue Scale, Hospital Anxiety and Depression Scale, Pain Catastrophizing Scale, Short-Form McGill Pain Questionnaire, Pain Disability Assessment Scale, pain drawings, and history of pain were collected. The patients were divided into two treatment outcome groups a year later: a good outcome group and a poor outcome group. [Results] One-hundred eighteen patients were allocated to the good outcome group. The scores for the Visual Analogue Scale, Pain Disability Assessment Scale, and affective subscale of the Short-Form McGill Pain Questionnaire and number of nonorganic pain drawings in the good outcome group were significantly lower than those in the poor outcome group. Duration of pain in the good outcome group was significantly shorter than in the poor outcome group. [Conclusion] These findings help better predict the efficacy of multidisciplinary treatments in chronic low back pain patients.

Key words: Chronic pain, Low back pain, Multidisciplinary treatments

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INTRODUCTION

Chronic low back pain (LBP) is one of the most common long-term health problems in adults in many countries. The prevalence of LBP in previous studies ranged from 18.6% to 57.4%¹⁻⁵. Investigation of chronic pain, including chronic LBP, has shifted from a purely biomedical model to a more holistic, biopsychosocial one⁶. There is strong evidence indicating that intensive multidisciplinary biopsychosocial treatments with a functional restoration approach have improved function when compared with inpatient or outpa-

tient non-multidisciplinary treatments⁷. Moreover, current guidelines generally advocate the use of multidisciplinary cognitive-behavioral and exercise rehabilitation programs as first-line treatments⁸. However, it has been difficult for clinicians to confirm efficacy, because chronic LBP is a complex, heterogeneous medical condition that includes a wide variety of symptoms⁹. Some studies showed associations of treatment outcome with patient characteristics, patient history, and psychological disturbance in chronic pain¹⁰⁻¹³. Therefore, further assessment of treatments for chronic LBP patients has been needed.

Our center is the first multidisciplinary pain center in Japan and was established in July 2007. To date, there have been no reports of the effects of multidisciplinary treatments on LBP in Japan. The purpose of this research was to show the associations among multidisciplinary treatment outcomes, pretreatment psychological factors, self-reported pain levels, and history of pain in chronic LBP patients.

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SUBJECTS AND METHODS

We included a total of 221 chronic LBP patients who visited the Pain Center of Aichi Medical University between January 2010 and December 2011. Chronic LBP is defined as back symptoms persisting for at least 3 months¹¹). Our Pain Center has anesthesiologists, orthopedists, psychiatrists, internists, dentists, nurses, physical therapists, and clinical psychotherapists. All patients were referred from other medical institutions. Upon presentation at our Pain Center for their first visit, the following data were collected for all patients: a set of standardized self-report measures, demographics, symptoms, duration of pain, education, and work status. Body mass index (BMI) was calculated from self-reported height and self-reported weight by a nurse. Education status was divided into three categories (junior high school, high school, and college). Work status was also divided into three categories (working, sick leave, and unemployed). These data were extracted from medical records after approval from the Ethics Committee of Aichi Medical University.

The 10-cm Visual Analogue Scale (VAS) (0 = no pain; 10 = worst pain imaginable) was used to obtain the average intensity of total pain. The Hospital Anxiety and Depression Scale (HADS) was designed to assess two separate dimensions of anxiety and depression. The HADS consists of 14 items, with the anxiety (HADS-A) and depression (HADS-D) subscales each including 7 items. A four-point response scale (from 0, representing absence of symptoms, to 3, representing maximum symptoms) was used, with possible scores for each subscale ranging from 0 to 21^{14, 15}). The HADS is designed to avoid the use of somatic symptoms that may confound other self-report measures of depression and anxiety^{14, 15}). The Pain Catastrophizing Scale (PCS) consists of 13 items, and subjects rate how frequently they have experienced such cognition/emotions^{16, 17}). The PCS is composed of three subscales: rumination (e.g., “I keep thinking about how much it hurts”), magnification (e.g., “I wonder whether something serious may happen”), and helplessness (e.g., “There is nothing I can do to reduce the intensity of the pain”)^{16, 17}). The total score of the PCS can range from 0 to 52^{16, 17}). The number of subjects who completed the PCS (n=101) was less than the number of subjects who completed the other self-report measures (n=221), as we have only recently begun to record it in our daily clinical practice. The Short-Form McGill Pain Questionnaire (SF-MPQ) is comprised of 15 descriptors of pain and two scales for rating pain intensity¹⁸). It is scored by summarizing all words used to describe pain (0–15) and by counting the intensity assigned to each word¹⁸). The sensory subscale of the SF-MPQ includes descriptors 1–11, while descriptors 12–15 represent affective interpretations¹⁸). The total score of the SF-MPQ ranged from 0 to 45¹⁸). The Pain Disability Assessment Scale (PDAS) assesses the degree to which chronic pain interfered with various daily activities during the past week¹⁹). It includes 20 items reflecting pain interference in a broad range of daily activities, and respondents indicate the extent to which pain interfered with activities¹⁹). Scores for the total PDAS range from 0 to 60, with higher scores indicating higher levels of pain interfer-

ence¹⁹). Pain drawings are commonly used to describe the location of pain reported by a patient. The pain drawings were classified according to the principles described in several previous studies^{20–22}), and scored with the nonorganic pain drawing scale on a scale of 1 to 4: 1 = organic; 2 = possibly organic; 3 = possibly nonorganic; 4 = nonorganic. The first author scored all pain drawings. Our previous study confirmed extremely high inter-rater agreement regarding the four classifications of the pain drawings²⁰). For ease of use, the organic and possibly organic drawings were pooled into an “organic” group, and those classified as nonorganic or possibly nonorganic were pooled into a “nonorganic” group as previously described^{20, 23, 24}).

We administered treatment after a medical conference attended by different types of professionals. As required, we administered pharmacological (including Kampo medicine, traditional Japanese herbal medicine²⁵), physical, acupuncture, cognitive-behavioral, and psychological treatments. Multidisciplinary treatment was based on the biopsychosocial model of illness focusing on the operant and cognitive-behavioral approach. The duration of treatment ranged from half an hour to an hour per visit. The frequency of visits ranged from 1 to 2 times per month. We excluded patients who had undergone surgery during the treatment period. Almost all patients were followed up a year later, at which time we recorded the VAS score. Data other than the VAS score were not recorded routinely in our daily clinical practice. We classified patients into two groups: a good outcome group, for patients whose pain level decreased by at least 50% according to the VAS score compared with before treatment, and a poor outcome group for patients whose pain level did not^{26–29}).

All data are expressed as the mean ± standard deviation of the mean (SD). The data were analyzed using the PASW Statistics software (version 18.0 for Windows, SPSS Inc, Chicago, IL, USA). The χ^2 test, Mann-Whitney U test, and Spearman’s rank correlation coefficient test were used for statistical analysis. $P < 0.05$ was considered statistically significant.

RESULTS

One-hundred eighteen patients (53.3%) were divided into the good outcome group, and 103 patients (46.7%) were divided into the poor outcome group. There were no significant differences in patient characteristics or daily life factors between the good outcome and poor outcome groups (Table 1). As shown in Table 2, the pretreatment scores for the VAS, HADS, PCS, SF-MPQ, PDAS, and pain drawings were compared between the outcome groups. Fewer subjects completed the PCS compared with the other self-report measures (Table 2). The HADS, sensory subscale of the SF-MPQ, and PCS scores did not show significant differences between the groups. On the other hand, the VAS, PDAS, and affective subscale of the SF-MPQ showed significantly lower scores in the good outcome group compared with the poor outcome group. Regarding the pain drawings, there were significantly fewer nonorganic pain drawings in the good outcome group (n=35/118) than in the poor outcome group (n=47/103). As shown in Table 3, characteristics

Table 1. Comparison of patient characteristics and daily life factors

	Good group (n = 118)	Poor group (n = 103)
Age	56.8 ± 16.7	58.1 ± 14.6
BMI	22.3 ± 3.3	22.4 ± 3.2
Gender		
Male	71 (60%)	67 (65%)
Female	47 (40%)	36 (35%)
Education history		
Junior high school	22 (19%)	18 (17%)
High school	48 (41%)	52 (51%)
College	39 (33%)	28 (27%)
No data	9 (7%)	5 (5%)
Work		
Working	43 (36%)	33 (32%)
Sick leave	13 (11%)	14 (14%)
Unemployment	62 (53%)	56 (54%)
Sleep disorder		
+	92 (78%)	81 (79%)
-	26 (22%)	22 (21%)
Drinking habit		
+	32 (27%)	28 (27%)
-	86 (73%)	75 (73%)
Smoking habit		
+	10 (8%)	11 (11%)
-	108 (92%)	92 (89%)
Exercising habit		
+	65 (55%)	57 (55%)
-	53 (45%)	46 (45%)

BMI: body mass index

Data for gender, education history, work, sleep disorder, drinking habit, smoking habit, and exercising habit are shown as numbers and percentages (in parentheses) of patients who replied subjectively with "yes." These data were analyzed by the χ^2 test.

Data for age and BMI are shown as the mean ± standard deviation of the mean (SD). These data were analyzed by the Mann-Whitney U test. The significance level is less than 5%.

There were no significant differences in patient characteristics and daily life factors between outcome groups.

of daily pain were investigated between the two outcome groups. The results showed that the number of patients who experienced pain at night in the good outcome group (n=25/118) was significantly lower than that in the poor outcome group (n=36/103). Furthermore, the number of patients who experienced pain in the morning in the good outcome group (n=33/118) was significantly greater than that in the poor outcome group (n=17/103). As shown in Table 4, the duration of pain in the good outcome group was significantly shorter than in the poor outcome group. The other items in the course of development of pain did not show significant differences between the two outcome groups (Table 4).

Table 2. Comparison of pretreatment scores for self-report measures between outcome groups

(A) VAS, SF-MPQ, HADS, PDAS, and pain drawings		
	Good group (n = 118)	Poor group (n = 103)
VAS	4.0 ± 2.9	4.8 ± 2.9 *
SF-MPQ		
Sensory	10.8 ± 5.7	12.4 ± 7.6
Affective	4.0 ± 3.4	5.4 ± 3.3 *
HADS		
Anxiety	8.3 ± 4.6	8.9 ± 4.3
Depression	8.3 ± 4.4	9.2 ± 4.8
PDAS	22.9 ± 13.6	28.2 ± 13.0 *
Pain drawings		*
Organic	83 (70%)	56 (54%)
Nonorganic	35 (30%)	47 (46%)
(B) PCS		
	Good group (n = 48)	Poor group (n = 53)
PCS		
Total score	33.1 ± 11.3	34.9 ± 9.1
Rumination	16.0 ± 4.2	16.6 ± 3.7
Magnification	6.5 ± 3.9	6.7 ± 3.0
Helplessness	10.6 ± 5.2	11.5 ± 4.5

VAS: Visual Analogue Scale; HADS: Hospital Anxiety and Depression Scale; SF-MPQ: Short-Form McGill Pain Questionnaire; PDAS: Pain Disability Assessment Scale; PCS: Pain Catastrophizing Scale

The number of patients differed between (A) and (B).

Data for the VAS, SF-MPQ, HADS, and PDAS in (A) and for the PCS in (B) are shown as the mean ± standard deviation of the mean (SD). These data were analyzed by the Mann-Whitney U test.

Data for pain drawings are shown as numbers and percentages (in parentheses) of the pooled patients. The data were analyzed by the χ^2 test.

The significance level is less than 5%.

*: Different between good and poor groups.

There were no significant differences in the scores for the HADS, sensory subscale of the SF-MPQ, and PCS between outcome groups. The scores for the VAS, PDAS, and affective subscale of the SF-MPQ were significantly lower in the good outcome group than in the poor outcome group.

Regarding pain drawings, there were significantly fewer nonorganic drawings in the good outcome group than in the poor outcome group.

DISCUSSION

In the present study, the pretreatment scores for the VAS, PDAS, affective subscale of the SF-MPQ, and pain drawings were associated with outcomes in the chronic LBP patients. Pretreatment status predicted treatment outcome in chronic pain patients¹⁰⁻¹³. This is the first report to show the association between the PDAS and multidisciplinary treatment outcomes. The PDAS reflects pain interference in a broad range of daily activities, and respondents indicate the extent

Table 3 . Characteristic of daily pain

	Good group (n = 118)	Poor group (n = 103)
Pain at rest		
+	77 (65%)	79 (77%)
-	41 (35%)	24 (23%)
Pain during motion		
+	61 (52%)	53 (51%)
-	57 (48%)	50 (49%)
Painful to the touch		
+	14 (12%)	16 (16%)
-	104 (88%)	87 (84%)
Pain changing with the weather		
+	91 (77%)	77 (75%)
-	27 (23%)	26 (25%)
Painful at night		*
+	25 (21%)	36 (35%)
-	93 (79%)	67 (65%)
Painful in the morning		*
+	33 (28%)	17 (17%)
-	85 (72%)	86 (83%)
Pain reduced in daytime		
+	11 (9%)	6 (6%)
-	107 (91%)	97 (94%)
Pain unaltered during day		
+	45 (38%)	47 (46%)
-	73 (62%)	56 (54%)
Pain changing during day		
+	55 (47%)	46 (45%)
-	63 (53%)	57 (55%)

Data for pain at rest, pain during motion, painful to the touch, pain changing with the weather, painful at night, painful in the morning, pain reduced in daytime, pain unaltered during day, and pain changing during day are shown as numbers and percentages (in parentheses) of patients who replied subjectively with "yes." These data were analyzed by the χ^2 test.

The significance level is less than 5%.

*: Different between good and poor groups.

There were significantly fewer patients reporting painful at night in the good outcome group than the poor outcome group. There were significantly more patients reporting painful in the morning in the good outcome group than the poor outcome group. There were no significant differences for the other characteristics between the outcome groups.

to which pain interferes with activities¹⁹). This might help us better predict the efficacy of multidisciplinary treatments in chronic LBP patients.

The results regarding the characteristics of daily pain revealed that the number of patients who experienced pain at night and the number of patients who experienced pain in the morning were significantly lower and higher, respectively, in the good outcome group than in the poor outcome group. These findings suggest that the patients who got progressively worse during the day had poor outcomes. The findings indicated that assessment of chronic LBP patients

Table 4. Course of development of pain

	Good group (n = 118)	Poor group (n = 103)
Duration of pain (y)		*
<1	45 (38%)	24 (23%)
≥1	73 (62%)	79 (77%)
Pain development		
By gradation)	66 (56%)	67 (65%)
Rapidly	52 (44%)	36 (35%)
Cause of injury		
Traffic accident	7 (6%)	9 (9%)
Work-related injury	1 (1%)	2 (2%)
Unclear	110 (93%)	92 (89%)

Data for duration of pain, pain development, and cause of injury are shown as numbers and percentages (in parentheses) of patients who replied subjectively with "yes." These data were analyzed by the χ^2 test.

The significance level is less than 5%.

*: Different between good and poor groups.

The durations of pain in the good outcome group were significantly shorter than those in the poor outcome group. There were no significant differences in the other items concerning the course of development of pain between the outcome groups.

could require not only psychological questionnaires but also standard medical interviews.

The pretreatment scores for catastrophizing were not consistently associated with the outcomes. In previous systematic reviews of nonspecific chronic LBP, although a decrease in catastrophizing was accompanied by an increase in daily activities and a decrease in pain levels, pretreatment scores for catastrophizing were not consistently associated with outcomes³⁰.

There were several limitations in this study. The multidisciplinary treatments offered in this study differed from the norm of offering 1–2 sessions per week for 6–12 consecutive weeks⁷). However, 53.3% of the patients were in the good outcome group in the present study, which was not much different from the rates in previous studies^{28, 31–33}). In addition, physical function and quality of life were not investigated after treatment in the present study. The treatment goals for the chronic pain patients were not only pain intensity. Further studies are needed using multidimensional outcomes. This study included only a small number of patients from a single medical center. Furthermore, the number of the subjects assessed with the PCS, was particularly small in the present study. The results of the present study must be interpreted with caution.

In conclusion, poor outcomes were related to high pretreatment scores for the VAS, PDAS, and affective subscale of the SF-MPQ; nonorganic pain drawings; longer duration of pain; and pain that progressively worsened for days in chronic LBP patients who received multidisciplinary treatments for a year.

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RESEARCH ARTICLE

Chronic Pain in the Japanese Community—Prevalence, Characteristics and Impact on Quality of Life

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Abstract

Background

Chronic pain is recognized as a public health problem that affects the general population physically, psychologically, and socially. However, there is little knowledge about the associated factors of chronic pain, such as the influence of weather, family structure, daily exercise, and work status.

Objectives

This survey had three aims: 1) to estimate the prevalence of chronic pain in Japan, 2) to analyze these associated factors, and 3) to evaluate the social burden due to chronic pain.

Methods

We conducted a cross-sectional postal survey in a sample of 6000 adults aged ≥ 20 years. The response rate was 43.8%.

Results

The mean age of the respondents was 57.7 years (range 20–99 years); 39.3% met the criteria for chronic pain (lasting ≥ 3 months). Approximately a quarter of the respondents reported that their chronic pain was adversely influenced by bad weather and also oncoming bad weather. Risk factors for chronic pain, as determined by a logistic regression model, included being an older female, being unemployed, living alone, and no daily exercise. Individuals with chronic pain showed significantly lower quality of life and significantly higher psychological distress scores than those without chronic pain. The mean annual duration of absence from work of working-age respondents was 9.6 days (range 1–365 days).

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Conclusions

Our findings revealed that high prevalence and severity of chronic pain, associated factors, and significant impact on quality of life in the adult Japanese population. A detailed understanding of factors associated with chronic pain is essential for establishing a management strategy for primary care.

Introduction

Chronic non-cancer pain is a common problem that substantially impairs physical and psychological health and economic well-being. A number of studies in recent years have attempted to improve understanding of the various characteristics of chronic pain, including its prevalence. Previous estimates of the prevalence of chronic pain in general populations have ranged from 7% [1] to 55% [2], but there have only been two notable surveys of chronic pain in Japan. Hattori et al. [3] found a prevalence of chronic pain of 13% in 2006 using a web-based survey. Their participants were subdivided into age groups (18–29 years, 30–49 years and ≥ 50 years), but the mean age of the entire group was not reported and the authors acknowledged that their use of the Internet might have excluded a greater proportion of elderly participants. Nakamura et al. [4] reported a prevalence of 15.4% in 2011 using a postal survey. Both studies used a definition of pain intensity as ≥ 5 on an 11-point numeric rating scale (NRS) and a pain duration of ≥ 6 months. This definition may be suitable for detecting the prevalence of severe dysfunctional persistent pain, but we aimed to identify the prevalence of more general chronic pain in the Japanese community, as persistent pain can cause substantial suffering and disability, even if it is mild or moderate. Therefore, we chose to use the International Association for the Study of Pain (IASP) definition of chronic pain of that “persisting continuously or intermittently for longer than 3 months”.

Although previous reports documented the clinical consequences of chronic pain, they did not explore the social consequences, such as work loss, or the negative effects of chronic pain on quality of life (QOL) and psychological well-being. To understand the various factors that may influence chronic musculoskeletal pain in a population, it is important to make comparisons within a community with similar levels of educational achievement, health awareness and social security provision, and that lives in a similar environment. A detailed understanding of the epidemiology of chronic pain is essential for efficient management of chronic pain to address its increasing social burden.

We examined the epidemiological characteristics of and influences on chronic pain in Japanese society by means of a postal survey. This cross-sectional study provided quantitative data on the prevalence and severity of various kinds of pain, the demographic characteristics of individuals with pain, the impact of pain on work, and the relationships between chronic pain, QOL and psychological distress in a community in which educational achievement, health awareness, social security provision and climate are well understood. The existence of a relationship between chronic pain and weather conditions is well known [5, 6], but few data on this phenomenon have been collected. Therefore, we also investigated the perceived influence of bad weather and cold temperature on pain in Japan.

Methods

Procedures and participants

We performed a postal survey in the well-defined primary health care district of Owariasahi in November 2011. Owariasahi is a highly industrialized community covering an area of 21.03 km² located in the northwest of Aichi, in the center of Honshu, Japan’s main island. The

community had 82,182 inhabitants (40,321 men; 41,816 women) and 33,326 households as of January 2013, according to the Japanese Basic Resident Register Network, a national registry of Japanese citizens. Distribution of demographic characteristics in the studied population, including age, male to female ratio, and composition of economy, had no notable deviation from nationwide census data of Japan [7] (S1 Table). These data were provided from the municipal government of Owariasahi with the approval of the municipal assembly as a part of a health improvement campaign. Owariasahi participated in the first Alliance for Healthy Cities in 2004, an international network supported by World Health Organization (WHO) to protect and enhance the health of city dwellers. The questionnaire was mailed to 6,000 individuals ≥ 20 years old. All participants were randomly selected using the Basic Resident Register Network. The study used a cross-sectional design and data were collected on 18 consecutive days.

The survey was reviewed and approved by the Owariasahi Education and Welfare Committee and the Owariasahi municipal council on September 2011.

Questionnaire

The questionnaire collected information on age, sex, occupation, co-residence and participation in exercise. Daily exercise was divided into three categories; “daily exercise”, “1–3 times/week” and “no regular exercise”. Participants were asked about pain intensity using an 11-point NRS (0 = no pain, 10 = worst pain imaginable), pain duration, location of pain and the perceived influence of local climate on pain symptoms.

Definition for chronic pain

Chronic pain was defined as a “yes” answer to the question, “Do you have any chronic pain lasting 3 months or more, either all the time or intermittently (excluding toothache, migraine, and menstrual pain)?” Participants who met these criteria were assigned to the chronic pain (CP) group. We defined severe chronic pain (severe CP) as persistent or regularly recurrent pain with a duration of >6 months and pain intensity on the NRS of ≥ 5 . The severe CP group was included as a subset of the CP group.

Impact of chronic pain

Subjective QOL was assessed on the ‘EuroQol-5 Dimensions’ scale (EQ-5D) [8], a common instrument for assessing health-related QOL (HRQOL) that was developed in Europe. This instrument contains descriptions of health status in five dimensions: ‘mobility’; ‘self-care’; ‘usual activities’; ‘pain/complaints’ and ‘anxiety/depression’. Participants are required to indicate whether they experience no, some, or serious health problems in each dimension. The combination of responses provides a description of 243 different health states, with a set of values ranging from 1 (no problem in any dimension) to -0.111 (severe problems in all five dimensions). All EQ-5D health states are assigned values on a scale between perfect health (1) and death (0), although the scoring rules permit scores <0 for extremely impaired health states. The Japanese version of the value set was developed by the Japanese EuroQol Translation Team, based on a survey of time trade-off assessments for the general population in Japan [9].

The Kessler 6-item psychological distress scale (K6) was also used [10], which consists of six questions to quantify non-specific psychological distress, with each question rated on a five-point scale. The K6 was scored using the unweighted sum of the responses, where responses ranged from “none of the time” = 0 to “all of the time” = 4. Thus, the total range of responses was 0–24. A K6 score over 5 is considered to be a risk factor for a mood disorder in the Japanese population [11].

To assess the social consequences of chronic pain, participants were asked to report the amount of time taken off work due to pain in the past year. Only data from participants 20–59 years old were included in this analysis, excluding students and unemployed persons. Overall work loss due to pain for the whole of Japan during 2012 was estimated on the basis of the 2012 annual report by the Japanese national tax agency, including number of employees, average working days and annual income.

Statistical analyses

Data were analyzed using SPSS version 21.0 for Windows (IBM Corp., Armonk, NY, USA). Descriptive statistics were used to present the demographic characteristics of the sample, as well as occupation, family composition, daily activity, and the location, severity and duration of chronic pain.

Continuous data are reported as the mean \pm standard deviation (SD) if normally distributed, and as the median and interquartile range (IQR) if not normally distributed. Analysis of variance, Student's unpaired t-test, and the Mann–Whitney U test were used where appropriate. Categorical data are represented as n (%), and were analyzed using Fisher's exact test.

Simultaneous logistic regression was performed to evaluate the effect of specific demographic characteristics and social factors, as well as disease variables, on pain status. The analysis produced odds ratios and their 95% confidence intervals. P values <0.05 were considered statistically significant in all analyses.

Results

Survey forms were completed and returned by 2,701 individuals, a response rate of 45.0%. Seventy-three respondents were excluded because of missing data, reducing the final sample size to 2,628 (43.8%). The respondents consisted of 1,104 men and 1,524 women (Table 1), with a mean age of 57.7 years (range 20–99 years).

The criteria for chronic pain were met by 1,032 respondents, an incidence of 39.3% among all respondents; severe chronic pain was reported by 456 respondents, equating to a prevalence of 17.4%. Chronic pain was more common in women (41.1%) than men (36.8%; $P < 0.05$). The questionnaire included employment status and family structure. Full time workers represented 30.8% of all respondents. More than half of all respondents (51.3%) were unemployed. 60% of respondents were living with three or more people, 8.2% of respondents lived alone (Table 1).

The prevalence of chronic pain increased with age from 22.2% to 52.6%, roughly in proportion to age, and was highest among patients in their nineties (Fig 1). The mean age of the CP group was significantly higher (60.9 ± 16.2 years) than that of the group without chronic pain (55.7 ± 17.4 years; $P < 0.001$).

Among the 1,032 respondents with chronic pain, the mean severity on an 11-point NRS was $5.2 \pm$ standard deviation 2.3, and 607 (58.5%) reported a pain intensity of 5 or more.

The mean severity of pain in the chronic pain (CP) group was 5.2 ± 2.3 . The severe CP group had an average pain severity of 6.7 ± 1.5 . The most common location of pain (one answer was allowed) was the lower back (30.6%) followed by the knees (19.8%), shoulders (17.0%) and neck (8.3%). Almost 40% of respondents had chronic spinal problems, including neck, middle back, and lower back pain, with more men reporting low back pain and more women reporting neck pain.

When asked under what conditions their chronic pain worsened or improved (Table 2), approximately 50% of respondents reported that their pain was influenced by environmental factors, with pain tending to be more intense in cold weather and less intense in warm weather.

Table 1. Social and demographic characteristics of all respondents, and those with or without chronic pain.

	All respondents (n = 2,628)	Without chronic pain (n = 1,596)	Chronic pain (n = 1,032)	Severe chronic pain (n = 456)
M/F, n/n (%/%)	1,104/1,524 (42.0%/58.0%)	698/898 (43.7%/56.3%)	406/626 (39.3%/60.7%)	159/297 (34.9%/65.1%)
Age (years)				
20–30, n (%)	185 (7.0%)	144 (9.0%)	41 (4.0%)	17 (3.7%)
31–40, n (%)	374 (14.2%)	263 (16.5%)	111 (10.8%)	46 (10.1%)
41–50, n (%)	345 (13.1%)	223 (14.0%)	122 (11.8%)	54 (11.8%)
51–60, n (%)	367 (14.0%)	201 (12.6%)	166 (16.1%)	77 (16.9%)
61–70, n (%)	673 (25.6%)	408 (25.6%)	265 (25.7%)	111 (24.3%)
71–80, n (%)	506 (19.3%)	270 (16.9%)	236 (22.9%)	111 (24.3%)
81–90, n (%)	159 (6.1%)	78 (4.9%)	81 (7.8%)	34 (7.5%)
91–100, n (%)	19 (0.7%)	9 (0.6%)	10 (1.0%)	6 (1.3%)
Occupation				
Full-time ^a	810 (30.8%)	535 (33.5%)	275 (26.6%)	114 (25.0%)
Primary sector	8 (1.0%)	4 (0.7%)	4 (1.5%)	2 (1.8%)
Secondary sector	274 (33.8%)	189 (35.3%)	85 (30.9%)	29 (25.4%)
Tertiary sector	528 (65.2%)	342 (63.9%)	186 (67.6%)	83 (72.8%)
Part-time	397 (15.1%)	253 (15.9%)	144 (14.0%)	57 (12.5%)
Student	34 (1.3%)	29 (1.8%)	5 (0.5%)	2 (0.4%)
Unemployed	1,349 (51.3%)	757 (47.4%)	592 (57.4%)	274 (60.1%)
Unknown	38 (1.4%)	22 (1.4%)	16 (1.6%)	9 (2.0%)
Family composition				
Living with ≥3 persons	1,578 (60.0%)	1,012 (63.4%)	566 (54.8%)	242 (53.1%)
Living as a couple	834 (31.7%)	478 (29.9%)	356 (34.5%)	154 (33.8%)
Living alone	216 (8.2%)	106 (6.6%)	110 (10.7%)	60 (13.2%)
Exercise				
Daily	622 (23.7%)	385 (24.1%)	237 (23.0%)	89 (19.5%)
1–3 days/week	1,006 (38.3%)	592 (37.1%)	414 (40.1%)	172 (37.7%)
None	942 (35.8%)	586 (36.7%)	356 (34.5%)	187 (41.0%)
Unknown	58 (2.2%)	33 (2.1%)	25 (2.4%)	8 (1.8%)
Duration of pain				
3–6 months	-	0 (0.0%)	284 (27.5%)	0 (0.0%)
6–12 months	-	0 (0.0%)	197 (19.1%)	111 (24.3%)
1–3 years	-	0 (0.0%)	194 (18.8%)	115 (25.2%)
>3 years	-	0 (0.0%)	357 (34.6%)	230 (50.4%)

^a Full-time workers were categorized as: primary (agriculture, forestry and fishery); secondary (mining, manufacturing and construction); or tertiary (service industries).

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One in four respondents claimed that their pain worsened before and during bad weather (rain, snow, storms, and typhoons).

The questionnaire also obtained information about daily exercise: 23.7% of respondents reported they exercised daily, 29.5% exercised 1–3 times a week, and the remaining 44.6% did no regular exercise. The daily exercise group reported a lower frequency of severe chronic pain (14.3%) than the groups that reported exercising 1–3 times/week (17.1%) or no regular exercise (19.9%; $P < 0.001$).

Individuals with chronic pain showed significantly lower utility values on the EQ-5D and higher K6 scores than those without chronic pain (Fig 2). The utility value of all respondents was 0.88 ± 0.16 . When the utility value of the EQ-5D was analyzed in relation to the presence