surgical and medical treatments, thereby improving medical skills.

Conflict of interest The authors declare that they have no conflict of interest.

References

1. Fukui M, Chiba K, Kawakami M, Kikuchi S, Konno S, Miyamoto M, Seichi A, Shimamura T, Shirado O, Taguchi T, Takahashi K, Takeshita K, Tani T, Toyama Y, Wada E, Yonenobu K, Tanaka T. Hirota, an outcome measure for patients with cervical myelopathy: Japanese Orthopaedic Association Cervical Myelopathy Evaluation Questionnaire (JOACMEQ): part 1. J Orthop Sci. 2007;12:227–40.
2. Japanese Orthopaedic Association score for cervical spondylotic myelopathy. J Jpn Orthop Assoc. 1975;99 (prefatory note in Japanese).
3. Revised Japanese Orthopaedic Association scores for cervical myelopathy. J Jpn Orthop Assoc. 1994;68:490–503 (in Japanese).
4. Fukui M, Chiba K, Kawakami M, Kikuchi S, Konno S, Miyamoto M, Seichi A, Shimamura T, Shirado O, Taguchi T, Takahashi K, Takeshita K, Tani T, Toyama Y, Wada E, Yonenobu K, Tanaka T, Hirota Y. Japanese Orthopaedic Association Cervical Myelopathy Evaluation Questionnaire (JOACMEQ): part 2. Endorsement of the alternative item. J Orthop Sci. 2007;12:241–8.
5. Fukui M, Chiba K, Kawakami M, Kikuchi S, Konno S, Miyamoto M, Seichi A, Shimamura T, Shirado O, Taguchi T, Takahashi K, Takeshita K, Tani T, Toyama Y, Yonenobu K, Wada E, Tanaka T, Hirota Y. Japanese Orthopaedic Association Cervical Myelopathy Evaluation Questionnaire (JOACMEQ): part 3. Determination of reliability. J Orthop Sci. 2007;12:321–6.
6. Fukui M, Chiba K, Kawakami M, Kikuchi S, Konno S, Miyamoto M, Seichi A, Shimamura T, Shirado O, Taguchi T, Takahashi K, Takeshita K, Tani T, Toyama Y, Yonenobu K, Wada E, Tanaka T, Hirota Y. Japanese Orthopaedic Association Cervical Myelopathy Evaluation Questionnaire (JOACMEQ): part 4. Establishment of equations for severity scores. J Orthop Sci. 2008;13:25–31.
7. Yonenobu K, Abumi K, Nagata K, Taketomi E, Ueyama K. Interobserver and intraobserver reliability of the Japanese Orthopaedic Association Scoring system for evaluation of cervical compression myelopathy. Spine. 2001;26:1890–5.
8. Fukui M, Chiba K, Kawakami M, Kikuchi S, Konno S, Miyamoto M, Seichi A, Shimamura T, Shirado O, Taguchi T, Takahashi K, Takeshita K, Tani T, Toyama Y, Yonenobu K, Wada E, Tanaka T, Hirota Y. JOA Back Pain Evaluation Questionnaire (JOABPEQ)/ JOA Cervical Myelopathy Evaluation Questionnaire (JOACMEQ). The report on the development of revised versions. J Orthop Sci. 2009;14:348–65

Validity and Reliability of the Japanese Version of the painDETECT Questionnaire: A Multicenter Observational Study

Yoshitaka Matsubayashi[1*], Katsushi Takeshita[1], Masahiko Sumitani[2], Yasushi Oshima[1], Juichi Tonosu[1], So Kato[1], Junichi Ohya[1], Takeshi Oichi[1], Naoki Okamoto[1], Sakae Tanaka[1]

1 Department of Orthopaedic Surgery, Faculty of Medicine, the University of Tokyo, Tokyo, Japan, **2** Department of Anesthesiology and Pain Relief Center, the University of Tokyo, Tokyo, Japan

Abstract

Objectives: The aim of this study was to evaluate the validity and reliability of the Japanese version of the painDETECT questionnaire (PDQ-J).

Materials and Methods: The translation of the original PDQ into Japanese was achieved according to the published guidelines. Subsequently, a multicenter observational study was performed to evaluate the validity and reliability of PDQ-J, including 113 Japanese patients suffering from pain.

Results: Factor analysis revealed that the main component of PDQ-J comprises two determinative factors, which account for 62% of the variance observed. Moreover, PDQ-J revealed statistically significant correlation with the intensity of pain (Numerical Rating Scale), Physical Component Score, and Mental Component Score of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). The Cronbach alpha for the total score was 0.78 and for the main component was 0.80. In the analysis of test–retest method, the intraclass correlation coefficient between the two scores was 0.94.

Conclusions: We demonstrated the validity and reliability of PDQ-J. We encourage researchers and clinicians to use this tool for the assessment of patients who suffer suspected neuropathic pain.

Citation: Matsubayashi Y, Takeshita K, Sumitani M, Oshima Y, Tonosu J, et al. (2013) Validity and Reliability of the Japanese Version of the painDETECT Questionnaire: A Multicenter Observational Study. PLoS ONE 8(9): e68013. doi:10.1371/journal.pone.0068013

Editor: Kazutaka Ikeda, Tokyo Metropolitan Institute of Medical Science, Japan

Received April 8, 2013; **Accepted** May 24, 2013; **Published** September 30, 2013

Funding: This study received financial funds from the "Health and Labour Sciences Research Grant." The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing interests: The authors have declared that no competing interests exist.

* E-mail: ymatsubayashi-tky@umin.ac.jp

Introduction

Neuropathic pain is defined as "pain caused by a lesion or disease of the somatosensory system" [1], and its prevalence reaches about 7%–8% in the European population [2,3]. A variety of diseases such as diabetic polyneuropathy, postherpetic neuralgia, spinal cord injury, and peripheral nerve compression cause neuropathic pain, and they generally follow a chronic course. Chronic pain in patients results in anxiety, depression, and interference with sleep, normal work, and social activities [4,5]. It has a strong negative impact on the quality of life [6] and has been estimated to result in an expense of more than $100 billion per year in direct medical costs and about $100 billion as indirect costs from absenteeism and decreased productivity at work in the United States [7]. Among chronic pain conditions, neuropathic pain impairs the quality of life profoundly, and patients with neuropathic pain are likely to generate more expenses compared with those with other pain conditions [8]. Although early and intense care of neuropathic pain is important, diagnosing neuropathic pain is a challenge because lesions of the somatosensory nervous system are not readily detectable. Unlike non-neuropathic pain conditions, neuropathic pain usually reveals characteristic symptoms such as "burning sensation," "prickling sensation," and/or a sensation of "electric shock [9]." On the basis of such characteristic descriptions, screening tools have been developed to identify the components of neuropathic pain from a patient's presentation of symptoms.

The painDETECT questionnaire (PDQ) is one of the screening tools of neuropathic pain, which was published by Freynhagen et al. from Germany [10,11]. They established the usefulness and validity of this brief, self-administered questionnaire in identifying neuropathic components of pain in patients with chronic lower back pain. PDQ has already been

Figure 1. The painDETECT Questionnaire–Japanese version (PDQ-J)

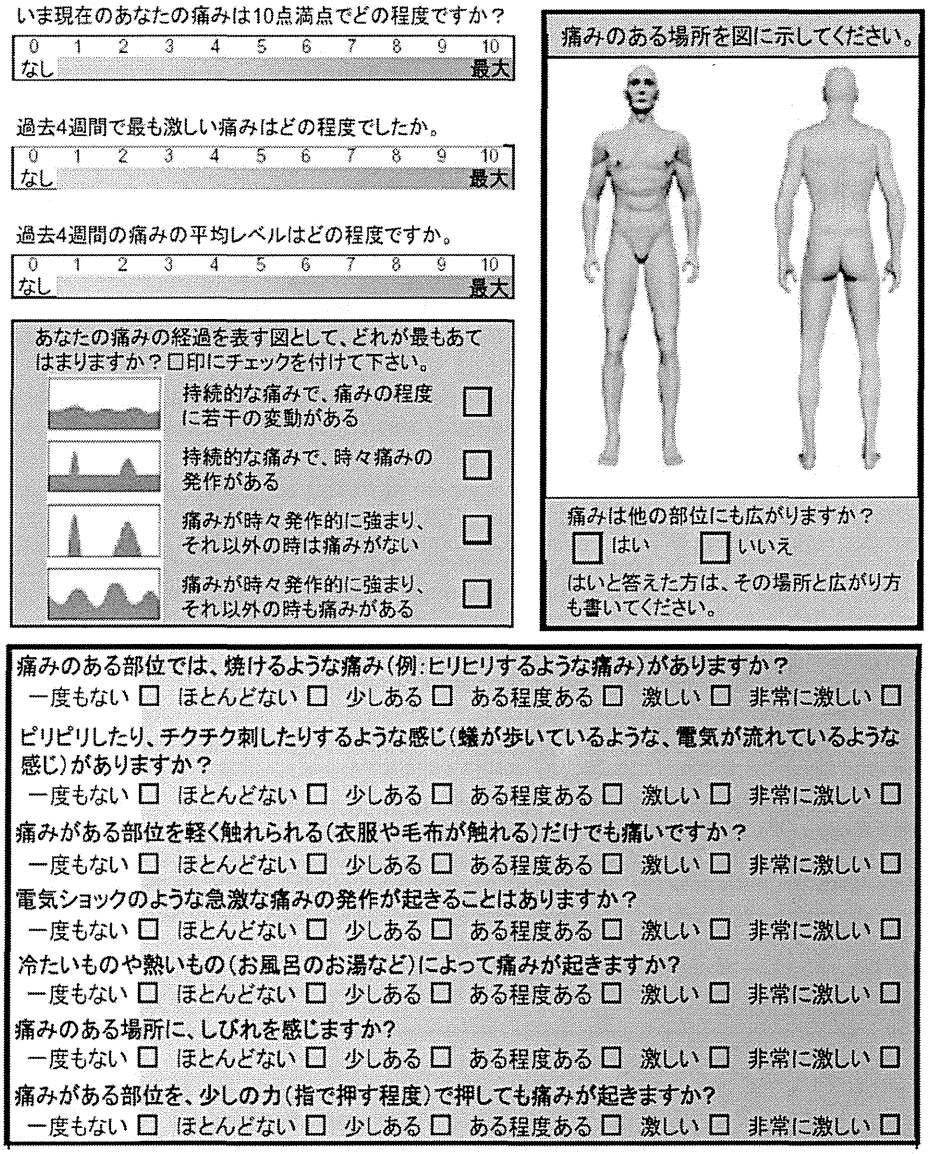

Figure 1. The painDETECT Questionnaire-Japanese version (PDQ-J).

doi: 10.1371/journal.pone.0068013.g001

translated into Spanish [12], Dutch [13], and Japanese [14]. The Japanese version of PDQ (PDQ-J) was translated and reported by one of the authors of the present study in 2007 (Figure 1). Translation and cross-cultural adaptation of PDQ-J was performed in accordance as per the established guidelines [15,16]. First, for forward translation, a professional native Japanese translator and a bilingual Japanese physician independently translated the original PDQ into Japanese. Second, an expert committee, including specialists in pain management, orthopedics, and methodology, conducted synthesis of the translation. Third, two native English translators, who were uninformed about the nature of the study, completed back translations of the translated PDQ; thereafter, back-translations were sent to the expert committee to detect any existing cultural bias, and the final version of PDQ-J was completed. Nevertheless, the validity of PDQ-J has not been confirmed yet; therefore, this study aimed to assess the validity and reliability of PDQ-J.

Materials and Methods

The study protocol was approved by the institutional review board of the Clinical Research Support Center of the University of Tokyo Hospital. Participants provided their written informed consent to participate in this study.

We conducted a multicenter observational study, and patients from two adult populations were enrolled. All the enrolled patients suffered from pain with an intensity of 3 or more out of 10 on an 11-point numerical rating scale (NRS). The first study group included patients with neuropathic pain (NeP group) diagnosed by a pain specialist in the pain center as per the guidelines established by the International Association for the Study of Pain (IASP) [17]. In the pain center, only neuropathic patients with stable disease condition and tolerable pain were selected; in addition, they were selected if it could be estimated that there would be little change in their pain during the study period. The second study group comprised patients suffering from acute nociceptive pain (NocP group) induced by trauma or orthopedic patients with a degenerative condition of the extremities. Moreover, patients with cultural or language barriers or with poor mental health status that prevented them from understanding or responding to proposed questions were excluded from this study. Informed consent was provided by selected patients from both the groups. In the first survey, all patients were asked to complete a set of questionnaires including PDQ-J, a three-type numeric rating scale (NRS) of pain (i.e., pain during the survey, a four-week average, and maximum pain experienced), and the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). The patients answered questions regarding their demographic data (e.g., age, sex, height, weight, occupation, smoking history, and education). Thereafter, the physicians reported the original diagnoses, comorbidities, and treatment options. The second survey questionnaire was administered only to the neuropathic patients 2–5 weeks after the first visit, and it included the same set of three questionnaires with one additional question regarding whether there was an increase, decrease, or no change in pain since the administration of the first survey.

PDQ comprises a main component along with two additional components. In the main component, termed as "gradation of pain," the patient is asked to identify the presence of seven pathological pain sensations: burning, tingling, or prickling sensations, tactile and thermal allodynia, electric shock-like sensations, numbness, and pressure-evoked pain sensation. The patient grades the presence of each type of pain as follows: 0 = never; 1 = hardly noticed; 2 = slightly; 3 = moderately; 4 = strongly; 5 = very strongly. This main component of PDQ yields scores from 0 to 35 points. A second component of PDQ, termed as "pain course pattern," is a multiple-choice questionnaire accompanied by four pain charts; the patient is asked to quantify the pattern of experienced pain as follows: persistent pain with slight fluctuations (0 points); persistent pain with pain attacks (−1 point); pain attacks without pain between them (1 point); pain attacks with pain between them (1 point). The third component of PDQ, termed "radiating pain," asks patients regarding radiation of pain to other regions of the body (2 points). A total score is calculated by adding the scores from the three components; a high score indicates that the pain is possibly neuropathic in nature.

The intensity of pain was assessed by a three-type NRS where the patient is asked to grade the actual pain level experienced, the maximum pain level experienced in the last four weeks, and the average pain level experienced in last four weeks on a scale of 0-10 (0 = no pain, 10 = worst pain imaginable).

The SF-36 consists of eight subscales, namely physical functioning, physical role functioning, bodily pain, general health perceptions, vitality, social role functioning, emotional role functioning, and mental health [18,19]. Each subscale is transformed to a score ranging from 0 to 100, with lower scores indicating poor health-related quality of life. For analysis, we used two summed scores: the Physical Component Score (PCS) and the Mental Component Score (MCS). Each score has the same mean and standard deviation (50 and 10, respectively) in a normal population.

Feasibility

We analyzed the number of unanswered questions to evaluate the feasibility of PDQ-J.

Validity

To establish construct validity, we performed an exploratory factor analysis with principal components extraction. The Kaiser criterion (eigenvalues > 1.0) and Scree plot were used to determine the number of factors. As for criterion-related validity, we calculated the Pearson correlation coefficient between PDQ-J, NRS, PCS (SF-36), and MCS (SF-36). Following are the generally accepted rankings for coefficients: 1.0–0.81 (excellent); 0.80–0.61 (very good); 0.60–0.41 (good); 0.40–0.21 (fair); and 0.20–0 (poor) [20].

Reliability

Internal consistency was measured with Cronbach's alpha. Alpha coefficients of a magnitude of ≥0.70 were considered useful as evidence of adequate scale reliability at the level of group comparisons [21]. Repeatability was assessed by a test–retest method. Retest was administered to neuropathic patients more than two weeks after first survey. Intraclass correlation coefficients (ICCs) between test and retest scores were calculated from the data from patients who responded with no change of symptoms between the two surveys; moreover, those with coefficients >0.80 were considered as having excellent reliability [22].

All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS version 21.0) software.

Results

A total of 122 Japanese patients were recruited in this study. However, nine patients were excluded because of incomplete responses to the proposed questions; most (six of nine) of the blank responses were to the question regarding the radiation of pain. Following exclusions, a total of 113 patients were further evaluated: 60 patients were diagnosed as having neuropathic

Table 1. Demographic data of study patients.

	NeP (n=60) (SD)	NocP (n=53) (SD)	P value (t-test)
Age (mean)	59 (15)	57 (18)	n.s.
Male/Female	40/20	30/23	n.s.
Height (mean)	164 (10)	164 (11)	n.s.
Weight (mean)	64 (17)	62 (13)	n.s.
Duration (months)	63 (71)	2.3 (7.9)	<0.001

NeP: Neuropathic Pain, NocP: Nociceptive Pain

doi: 10.1371/journal.pone.0068013.t001

Table 2. Demographic data of study patients (education).

Education	NeP (n)	NocP (n)
Middle school	8	11
High school	24	14
Junior college	6	13
University	16	15
Graduate university	4	0

NeP: Neuropathic Pain, NocP: Nociceptive Pain

doi: 10.1371/journal.pone.0068013.t002

Table 3. Demographic data of study patients (occupation).

Occupation	NeP (n)	NocP (n)
Employee	15	18
Retired	19	12
Self-employed	11	9
Housewife	8	8
Part-time job	3	6
Student	1	0
Employer	1	0

NeP: Neuropathic Pain, NocP: Nociceptive Pain

doi: 10.1371/journal.pone.0068013.t003

pain, and 53 were categorized as having nociceptive pain. The demographic characteristics of these patients are presented in Tables 1, 2, and 3; in addition, it lists specific etiologies of pain in patients in the NeP group [brachial plexus injury (12 patients); radiculopathy (12 patients); herpes zoster (11 patients); spinal cord injury (10 patients); diabetic or alcoholic polyneuropathies (7 patients); phantom pain (5 patients); complex regional pain syndrome (CRPS; 2 patients); carpal tunnel syndrome (1 patient); and thalamic pain (1 patient)] and the NocP group [trauma in 47 patients (89%), and degenerative diseases in 6 patients (11%)] (Table 4). Specific etiologies included fractures (32 patients), contusion/sprains (10 patients), osteoarthritis (4 patients), muscle pain (3 patients), dislocations (2 patients), tenosynovitis (1 patient), and rotator cuff injury (1 patient).

Tables 5 and 6 presents the summary of patient responses of PDQ-J, and Table 7 presents the scores for each questionnaire in NeP and NocP group, respectively. On the

Table 4. Etiology of study patients.

Neuropathic Pain	Nociceptive Pain
Brachial Plexus Injury 12, Radiculopathy 12, Herpes zoster 11, Spinal cord injury 10, Neuropathy 7, Phantom pain 5, complex regional pain syndrome 2, Carpal Tunnel Syndrome 1, Thalamic pain 1	Fracture 32, Contusion/sprain 10, Osteoarthritis 4, Muscle pain 3, Dislocation 2, Tenosynovitis 1, Rotator cuff injury 1

doi: 10.1371/journal.pone.0068013.t004

Table 5. PainDETECT Questionnaire-Japanese version (PDQ-J): summary of patient responses (Q1-7).

n (NeP/NocP)	No	Hardly noticed	Slightly	Moderately	Strongly	Very strongly
Q1. Burning	14 (4/10)	25 (11/14)	30 (9/21)	21 (17/4)	18 (14/4)	5 (5/0)
Q2. Tingling	10 (0/10)	12 (6/6)	39 (13/26)	25 (17/8)	19 (18/1)	8 (6/2)
Q3. Pain by touch	17 (8/9)	30 (15/15)	24 (10/14)	21 (12/9)	15 (12/3)	6 (6/2)
Q4. Electric shock-like pain	28 (9/19)	34 (16/18)	18 (11/7)	18 (12/6)	9 (8/1)	6 (4/2)
Q5. Pain on cold/hot stimulation	33 (8/25)	40 (23/17)	19 (12/7)	15 (12/3)	2 (2/0)	4 (3/1)
Q6. Numbness	15 (1/14)	23 (5/18)	19 (7/12)	19 (13/6)	18 (17/1)	19 (17/2)
Q7. Pain by pressure	5 (3/2)	28 (18/10)	22 (8/14)	26 (14/12)	19 (10/9)	13 (7/6)

NeP: Neuropathic Pain, NocP: Nociceptive Pain

doi: 10.1371/journal.pone.0068013.t005

pain intensity scale, patients from the NeP group experienced pain that was significantly more severe compared with that in the NocP group. The PDQ-J and SF-36 scores revealed similar trends: patients in the NeP group revealed lower physical and mental functioning compared with that in patients in the NocP group.

Validity

The factor analysis by Promax rotation using the Kaiser criterion (eigenvalues ≥1.0) and a Scree plot revealed that the main component of PDQ-J consists of two determinative factors, and it explained 62% of the variance. One of these determinative factors can be termed as "spontaneous pain," and the other as "evoked pain." For criterion-related validity, the total score of PDQ-J revealed statistically significant correlations with pain intensity, PCS (SF-36), and MCS (SF-36; Table 8).

Table 6. PainDETECT Questionnaire-Japanese version (PDQ-J): summary of patient responses (Q8-9).

Q8. Pain course pattern	n (NeP/NocP)
Persistent pain with slight fluctuations	46 (22/24)
Persistent pain with pain attacks	21 (12/9)
Pain attacks without pain between them	18 (3/15)
Pain attacks with between them	28 (23/5)
Q9. Radiating pain	**n (NeP/NocP)**
Yes	74 (35/39)
No	34 (23/11)

NeP: Neuropathic Pain, NocP: Nociceptive Pain

doi: 10.1371/journal.pone.0068013.t006

Table 7. Scores of Pain Intensity, Neuropathic pain, and health-related outcomes.

Outcomes	NeP (SD)	NocP (SD)	P-value (t-test)
Pain Intensity-NRS (present)	6.5 (2.3)	4.3 (2.9)	< 0.001
Pain Intensity-NRS (average)	6.7 (2.0)	4.2 (2.3)	< 0.001
Pain Intensity-NRS (maximum)	8.3 (1.6)	6.6 (3.2)	< 0.001
painDETECT	18.6 (6.3)	11.8 (6.3)	< 0.001
PCS (SF-36)	26.6 (16.9)	34.3 (20.8)	< 0.05
MCS (SF-36)	41.6 (11.7)	52.7 (10.2)	< 0.001

NeP: Neuropathic Pain, NocP: Nociceptive Pain, NRS: Numerical Rating Scale, SF-36: Medical Outcomes Study 36-Item Short-Form Health Survey, PCS: Physical Component score, MCS: Mental Component Score

doi: 10.1371/journal.pone.0068013.t007

Table 8. Pearson correlation coefficient with PDQ-J.

	PDQ-J	P Value
Pain-Intensity (NRS)	0.44	< 0.01
PCS (SF-36)	−0.27	< 0.01
MCS (SF-36)	−0.34	< 0.01

NeP: Neuropathic Pain, NocP: Nociceptive Pain, NRS: Numerical Rating Scale, SF-36: Medical Outcomes Study 36-Item Short-Form Health Survey, PCS: Physical Component score, MCS: Mental Component Score

doi: 10.1371/journal.pone.0068013.t008

Reliability

The Cronbach alpha for the total score of PDQ-J was 0.78 and that of the main component of PDQ (i.e., "gradation of pain") was 0.80, which was comparable to 0.83 and 0.86 reported in the original and Spanish versions, respectively [11,12]. The score for each of the nine questions in PDQ-J revealed a statistically significant correlation with the total score of PDQ-J. We could recruit 16 patients with neuropathic pain for a test–retest study; of these, 11 patients reported no change in their symptoms, and the data for each these patients were evaluated. The average period between the two surveys was 23.1 days [standard deviation (SD): 8.3]. The mean score of the first and second survey was 20.4 (SD: 7.7) and 20.2 (SD: 7.2), respectively. Furthermore, ICC between the two scores was 0.94 despite the relatively long interval between the two surveys (Figure 2).

Figure 2.

Relationship between results of first and second PDQ-J scores in the retested patients

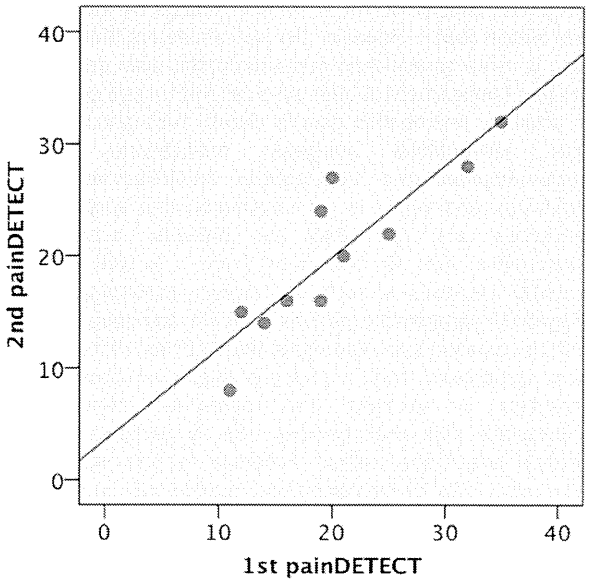

Figure 2. Relationship between results of first and second PDQ-J scores in the retested patients.

doi: 10.1371/journal.pone.0068013.g002

Discussion

This study demonstrated that PDQ-J has good validity and reliability. In addition, the results obtained in this study were comparable with those obtained in previous studies [11,12]. With regard to construct validity, the factor analysis revealed that the seven Likert items of PDQ-J consist of two determinative factors, which could be designated as "spontaneous pain" and "evoked pain." These factors are consistent with clinical characteristics of neuropathic pain. Further, with regard to criterion-related validity, the correlation between PDQ-J and NRS, MCS (SF-36), and PCS (SF-36) was moderate, indicating that PDQ-J can reflect pain intensity as well as impairments of mental status and physical status of individual patients. There is evidence from a previous study to support this, in which patients with more intense pain revealed higher total scores on PDQ [23]. Therefore, PDQ-J might be used as a score of pain severity, although another study should be conducted to validate this. In this study, we demonstrated fair to good criterion-related validity, excellent internal consistency, and high reliability with statistical significance, although the number of patients was limited, particularly in the

analysis of repeatability. As this study evaluated two distinct types of pain, neuropathic and acute nociceptive pain in the extremities, the methods and results obtained in this study might be useful in a wide patient population suffering from various types of pain.

Because the prevalence of patients with neuropathic pain is limited in general population [24], neuropathic pain has not been still recognized well in clinical settings all over the world and also in Japan. However, the indications are that this type of pain is more severe than non-neuropathic pain and results in profound impairment of both physical and mental quality of life. In addition, neuropathic pain is usually resistant to treatment with conventional analgesic medications such as acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs), and yet, it is not uncommon that such ineffective measures are prescribed for patients suffering from neuropathic pain. On the other hand, it is well known that specific medications such as tricyclic antidepressants and pregabalin/gabapentine provide effective analgesia in patients with neuropathic pain. Therefore, the detection of a neuropathic pain component from a patient's total pain presentation is important in selecting the appropriate medication for appropriate pain management; this is particularly true for general physicians without expertise in pain management. Screening tools for identifying neuropathic pain, such as PDQ, have revealed that a neuropathic pain component is underdiagnosed in a profound number of patients with pain, thereby suggesting that patients with neuropathic pain are not administered analgesics that are most effective in treating this type of pain. Similar circumstances are probably present in Japan as well. The results of the present study along with confirmed reliability and validity of PDQ-J provide the rationale to encourage extension of its use by general physicians in Japan to promote appropriate pain management in patients suffering with conditions involving chronic pain.

Conclusion

This study confirms that PDQ-J has good reliability and validity as a pain assessment tool. Thus, we encourage researchers and clinicians to use PDQ-J for the assessment of patients suffering from pain that is suspected to be neuropathic in origin.

Author Contributions

Conceived and designed the experiments: KT MS. Performed the experiments: YM KT MS YO SK JO TO NO ST JT. Analyzed the data: KT YM. Wrote the manuscript: YM KT MS.

References

1. Jensen TS, Baron R, Haanpää M, Kalso E, Loeser JD et al. (2011) A new definition of neuropathic pain. Pain 152: 2204-2205. doi:10.1016/j.pain.2011.06.017. PubMed: 21764514.
2. Torrance N, Smith BH, Bennett MI, Lee AJ (2006) The epidemiology of chronic pain of predominantly neuropathic origin. Results from a general population survey. J Pain 7: 281-289. doi:10.1016/j.jpain.2005.11.008. PubMed: 16618472.
3. Bouhassira D, Lantéri-Minet M, Attal N, Laurent B, Touboul C (2008) Prevalence of chronic pain with neuropathic characteristics in the general population. Pain 136: 380-387. doi:10.1016/j.pain.2007.08.013. PubMed: 17888574.
4. Galer BS, Gianas A, Jensen MP (2000) Painful diabetic polyneuropathy: epidemiology, pain description, and quality of life. Diabetes Res Clin Pract 47: 123-128. doi:10.1016/S0168-8227(99)00112-6. PubMed: 10670912.
5. Rodríguez MJ, Díaz S, Vera-Llonch M, Dukes E, Rejas J (2007) Cost-effectiveness analysis of pregabalin versus gabapentin in the management of neuropathic pain due to diabetic polyneuropathy or post-herpetic neuralgia. Curr Med Res Opin 23: 2585-2596. doi:10.1185/030079907X233151. PubMed: 17875242.
6. Gálvez R, Marsal C, Vidal J, Ruiz M, Rejas J (2007) Cross-sectional evaluation of patient functioning and health-related quality of life in patients with neuropathic pain under standard care conditions. Eur J Pain Engl, 11: 244-255. PubMed: 16563819.
7. McCarberg BH, Billington R (2006) Consequences of neuropathic pain: quality-of-life issues and associated costs. Am J Manag Care United States, 12: S263-S268. PubMed: 16774458.
8. O'Connor AB (2009) Neuropathic pain: quality-of-life impact, costs and cost effectiveness of therapy. Pharmacoeconomics. 27: 95-112. doi:10.2165/00019053-200927020-00002. PubMed: 19254044.
9. Attal N, Fermanian C, Fermanian J, Lanteri-Minet M, Alchaar H et al. (2008) Neuropathic pain: are there distinct subtypes depending on the aetiology or anatomical lesion? Pain 138: 343-353. doi:10.1016/j.pain.2008.01.006. PubMed: 18289791.
10. Freynhagen R, Tolle TR, Baron R (2005) painDETECT–ein Palmtopbasiertes Verfahren fur Versorgungsforschung, Qualitatsmanagement und Screening bei chronischen Schmerzen. Akt Neurol 34: 641.
11. Freynhagen R, Baron R, Gockel U, Tölle TR (2006) painDETECT: a new screening questionnaire to identify neuropathic components in patients with back pain. Curr Med Res Opin 22: 1911-1920. doi:10.1185/030079906X132488. PubMed: 17022849.
12. De Andrés J, Pérez-Cajaraville J, Lopez-Alarcón MD, López-Millán JM, Margarit C et al. (2012) Cultural adaptation and validation of the painDETECT scale into Spanish. Clin J Pain 28: 243-253. doi:10.1097/AJP.0b013e31822bb35b. PubMed: 21926908.
13. Timmerman H, Wolff AP, Schreyer T, Outermans J, Evers AW et al. (2013) Cross-Cultural Adaptation to the Dutch Language of the PainDETECT-Questionnaire. Pain Pract 13: 206-214. PubMed: 22776283.
14. Sumitani M, Yamada Y (2007) Chapter 2. Neuropathic Pain. Management of chronic pain-category of chronic pain and, definition, diagnosis and pharmacotherapy of neuropathic pain. Tokyo: Excerpta Medica. pp. 7-19 (in Japanese)
15. Guillemin F, Bombardier C, Beaton D (1993) Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. J Clin Epidemiol 46: 1417-1432. doi:10.1016/0895-4356(93)90142-N. PubMed: 8263569.
16. Beaton DE, Bombardier C, Guillemin F, Ferraz MB (2000) Guidelines for the process of cross-cultural adaptation of self-report measures. Spine (Phila Pa 1976) 25: 3186-3191 PubMed: 11124735.
17. Treede RD, Jensen TS, Campbell JN, Cruccu G, Dostrovsky JO et al. (2008) Neuropathic pain: redefinition and a grading system for clinical and research purposes. Neurology 70: 1630-1635. doi:10.1212/01.wnl.0000282763.29778.59. PubMed: 18003941.
18. McHorney CA, Ware JE Jr., Raczek AE (1993) The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. Med Care. 31: 247-263. doi:10.1097/00005650-199303000-00006. PubMed: 8450681.
19. Fukuhara S, Ware JE Jr., Kosinski M, Wada S, Gandek B (1998) Psychometric and clinical tests of validity of the Japanese SF-36 Health Survey. J Clin Epidemiol England, 51: 1045-1053. PubMed: 9817122.
20. Feise RJ, Michael Menke J (2001) Functional rating index: a new valid and reliable instrument to measure the magnitude of clinical change in spinal conditions. Spine (Phila Pa 1976) 26: 78-86 PubMed: 11148650.
21. Nunnally JC, Bernstein IH (1994) Psychometric Theory. New York: McGraw-Hill.
22. Shrout PE, Fleiss JL (1979) Intraclass correlations: uses in assessing rater reliability. Psychol Bull 86: 420-428. doi:10.1037/0033-2909.86.2.420. PubMed: 18839484.

23. Schmidt CO, Schweikert B, Wenig CM, Schmidt U, Gockel U et al. (2009) Modelling the prevalence and cost of back pain with neuropathic components in the general population. Eur J Pain 13: 1030-1035. doi: 10.1016/j.ejpain.2008.12.003. PubMed: 19201230.

24. Bouhassira D, Lantéri-Minet M, Attal N, Laurent B, Touboul C (2008) Prevalence of chronic pain with neuropathic characteristics in the general population. Pain 136: 380-387. doi:10.1016/j.pain.2007.08.013. PubMed: 17888574.

Mod Rheumatol
DOI 10.1007/s10165-013-0876-1

ORIGINAL ARTICLE

Prevalence of low back pain as the primary pain site and factors associated with low health-related quality of life in a large Japanese population: a pain-associated cross-sectional epidemiological survey

Koji Yamada · Ko Matsudaira · Katsushi Takeshita · Hiroyuki Oka · Nobuhiro Hara · Yasuo Takagi

Received: 27 December 2012 / Accepted: 25 March 2013

Abstract
Objectives This study aimed to estimate the prevalence, magnitude, and direction of the associations among disability, pain intensity, number of pain sites, and health-related quality of life (HRQoL) in patients reporting low back pain (LBP) as their primary pain.
Methods In January 2009, an Internet survey was performed for randomly selected adults aged 20–79 years who were registered as Internet research volunteers. Of 20 044 respondents, individuals with LBP as the primary pain were analyzed for associations among disability, number of pain sites, and HRQoL. Factors associated with low HRQoL were examined using multiple logistic regression modeling.
Results Of the 20 044 respondents, 25.2 % ($n = 5060$) reported LBP and 13.5 % ($n = 2696$) reported LBP as their primary pain. Among those with LBP as the primary pain, HRQoL decreased with increase in disability and number of pain sites. In multivariate analyses, disability [adjusted odds ratio (aOR), 2.93–4.58], number of pain sites (aOR, 1.42–6.12), pain intensity ≥ 7 (aOR, 1.88), and age ≥60 years (aOR, 1.55) were associated with low HRQoL.
Conclusions Approximately 13.5 % of patients reported LBP as their primary pain. Disability with absence from social activity and ≥7 pain sites were strongly associated with low HRQoL.

Keywords Disability · EQ-5D · Low back pain · Multisite pain · Sick leave

K. Yamada (✉) · K. Takeshita · N. Hara
Department of Orthopaedic Surgery, Faculty of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan
e-mail: forpatients2008@gmail.com

K. Matsudaira
Clinical Research Center for Occupational Musculoskeletal Disorders, Kanto Rosai Hospital, Kawasaki, Kanagawa, Japan

H. Oka
Department of Joint Disease Research, 22nd Century Medical and Research Center, The University of Tokyo, Tokyo, Japan

Y. Takagi
Graduate School of Health Management, Keio University, Fujisawa, Kanagawa, Japan

Introduction

Low back pain (LBP) is a common [1], costly [2], and, at times, disabling [3] condition that can lead to disability and sick leave from work or school. Pain at this site often fluctuates over time with frequent recurrences or exacerbations [4, 5]. The prevalence of LBP has been reported to range from 12–33 % [4] due to the methodologic heterogeneity across LBP prevalence studies [6, 7]. LBP is the most frequent and most expensive cause of work-related disability [8] and can affect health-related quality of life (HRQoL). LBP is a part of musculoskeletal pain [9, 10], but only one-sixth to one-third of individuals who suffer from LBP have LBP as their only pain source. Most LBP respondents also have pain at other sites [10]; this pain could be the primary reason for their disability. Moreover, a positive correlation was reported between the number of pain sites and functional problems in a large clinical study [9]. However, the prevalence and the impact of working disability and number of pain sites on HRQoL in those who have LBP as the primary pain have not been well examined.

Published online: 10 April 2013

Therefore, the aim of this study was to estimate the prevalence, magnitude, and direction of the associations among disability, pain intensity, number of pain sites, and HRQoL in those reporting LBP as their primary pain in the pain-associated cross-sectional epidemiological (PACE) survey, which covers a large Japanese population.

Materials and methods

Subjects

The PACE survey was a cross-sectional Internet survey designed to evaluate the prevalence and characteristics of musculoskeletal pain in a large Japanese population. The study was performed over 10–18 January, 2009. Respondents were recruited at random from 1 477 585 research volunteers who were registered with an Internet survey company (Rakuten Research Inc., Tokyo, Japan), consistent with the Japanese demographic composition [11]. An invitation to participate in the research was sent through an e-mail containing a link to the survey. Double registration was prevented by checking the e-mail address and disabling the link to the questionnaire once the responder completed the survey. Forms were configured to automatically reject incomplete questionnaires. An additional credit point for Internet shopping was given as a financial incentive to the responders. On 18 January, 2009, the survey was closed when the number of respondents reached 20 063; thus, the response rate is not relevant in this survey. Individuals whose reported age was <20 years or >79 years were excluded; thus, 20 044 participants were retained. This study was approved by Keio University's institutional review board.

Measures

The questionnaire included questions regarding musculoskeletal pain in the previous month and various individual factors. The respondents were asked about the characteristics of their musculoskeletal pain, such as the pain site(s), pain intensity at each site, site of the primary pain, duration of the primary pain, and disability due to the primary pain. Pain intensity was scored with a numeric rating scale (NRS) comprising 11 points (0 = no pain, 10 = worst pain imaginable). Disability was classified into three categories using a modified graded chronic pain scale (GCPS) [12], based on disability for social activity, such as work, school, and housework. Those with LBP and no disability were classified as modified GCPS grade 1, those with LBP and disability for social activity as modified GCPS grade 2, and those with LBP and disability leading to absence from social activity as modified GCPS grade 3. Respondents were asked about their demographic characteristics, including age, sex, occupational status, and HRQoL. HRQoL was measured using the Japanese EQ-5D instrument [13].

Definition of LBP

LBP was defined as pain experienced (over the previous month) below the costal margin and above the inferior gluteal folds, as described on the full-body manikin (Fig. 1, site 13), excluding those with pain around the anus (Fig. 1, site 21). Chronic LBP was defined as pain lasting ≥3 months.

EQ-5D

The EQ-5D instrument is a standardized general system for describing and valuing HRQoL [14]. It has good reliability and validity, and comprises five dimensions (mobility, self-care, usual activity, pain/discomfort, anxiety/depression) that are rated on three levels (1 = no problem, 2 = some problem, 3 = extreme problem); thus, it generates 243 theoretically possible health states (11111 = full health, 33333 = most extreme state).

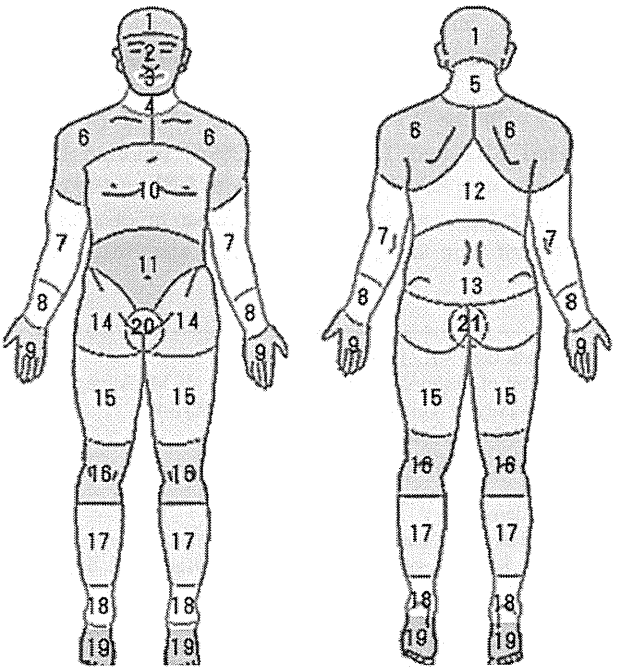

Fig. 1 The full-body manikin used in the pain-associated cross-sectional epidemiological (PACE) survey. Low back pain was defined as pain experienced below the costal margin and above the inferior gluteal folds, described as site number 13, excluding those with pain around the anus (site number 21)

Statistical analysis

First, the 1-month prevalence was calculated for those who had any LBP, LBP as the primary pain, and LBP as the only pain source (localized LBP). Further analyses were performed for those reporting LBP as their primary pain site using SPSS version 18 (IBM Corp., Armonk, N.Y., USA). Spearman's rho correlation coefficient was used to assess the correlations among HRQoL (EQ-5D score), disability, number of pain sites (other than LBP), and pain intensity (NRS score). For logistic regression analysis, the lowest 20 % of the EQ-5D scores in the total study population of the PACE survey was used as the dependent variable. A two-sided 5 % significance level was used in all statistical tests.

Results

LBP prevalence

Of the 20 044 respondents, 9746 (48.6 %) were men, and the overall mean score on the EQ-5D was 0.850 [standard error (SE), 0.001] with a ceiling effect of 45.7 % (9165 respondents; Table 1). The 1-month prevalence of LBP was 25.2 % (5060 respondents), of which only approximately half (2696 respondents; 13.5 % of all respondents) reported LBP as their primary pain and about one-seventh (706 respondents; 3.5 % of all respondents) reported LBP as their only pain source.

Table 1 Characteristics of the total study population (n = 20,044)

Characteristic	n (%)
Age group (years)	
20–29	1,981 (9.9)
30–39	3,903 (19.5)
40–49	3,923 (19.6)
50–59	4,328 (21.6)
60–69	4,126 (20.6)
70–79	1,783 (8.9)
Mean ± SD	49.0 ± 14.2
Sex	
Male	9,746 (48.6)
Occupational status	
Worker	10,597 (52.9)
Housework and/or retired	7,655 (38.2)
Other (including student)	1,792 (8.9)
LBP prevalence	
Any LBP[a]	5,060 (25.2)
LBP as primary pain[b]	2,696 (13.5)
Localized LBP[c]	706 (3.5)
EQ5D score, mean ± SE	0.850 ± 0.001
Ceiling effect	9,165 (45.7)

LBP Low back pain, *SE* standard error

[a] Prevalence of respondents with LBP

[b] Prevalence of respondents with LBP as the primary pain site

[c] Prevalence of respondents with LBP as the only pain source

HRQoL in those with LBP as the primary pain

Further analyses were conducted for those with LBP as their primary pain. Of the 2696 respondents who reported LBP as the primary pain, 53.8 % (n = 1,424) were men, 78.1 % (n = 2,106) had chronic pain, 55.3 % (n = 1,491) reported LBP and no disability (modified GCPS grade 1), and 44.7 % (n = 1,205) reported disability for social activity with or without absence from social activity (Table 2). The mean EQ-5D score was 0.776 (SE, 0.003), which was significantly lower than that of the total study population (unpaired t test, $P < 0.01$).

Next, the associations among HRQoL, number of pain sites, and pain intensity according to disability were analyzed (Table 3). We found that HRQoL decreased (Spearman's rank correlation coefficient, −0.371; $P < 0.01$) while pain intensity increased (Spearman's rank correlation coefficient, 0.418; $P < 0.01$) with higher disability. An increase in the number of pain sites was seen only between grade 1 and grade 2 disabilities (Table 3). Based on further evaluation of HRQoL stratified by age, sex, and disability, mean EQ-5D scores generally were lower in those with higher age and higher disability, and in women (Table 4).

Further analyses were conducted to evaluate the association among each variable stratified by the number of pain sites (Table 5). The number of respondents with LBP as a part of multisite pain was approximately 6.2 times larger than the number of those with localized LBP. In this analysis, HRQoL showed a negative correlation with the number of pain sites (Spearman's rank correlation coefficient, −0.256; $P < 0.01$). HRQoL was highest when the pain was localized, and lowest when the number of pain sites was $\geq$ 7. The proportion of those with disability for social activity (modified GCPS grades 2 and 3) and pain intensity also showed a positive correlation with the number of pain sites (Spearman's rank correlation coefficient, 0.184 and 0.359, respectively; both $P < 0.01$).

Factors associated with low HRQoL

In multivariate analyses adjusted by modified GCPS, number of pain sites, sex, age, and pain intensity, all the variables except sex were positively associated with low HRQoL (Table 6). The odds were higher as both disability and number of pain sites increased. Disability with absence

Table 2 Overall and by sex characteristics of respondents with LBP as the primary pain

Characteristic	Overall, *n* (%; *n* = 2696)	Men, *n* (%; *n* = 1424)	Women, *n* (%; *n* = 1272)
Age group (years)			
20–29	196 (7.3)	80 (5.6)	116 (9.1)
30–39	476 (17.7)	229 (16.1)	247 (19.4)
40–49	597 (22.1)	298 (20.9)	299 (23.5)
50–59	596 (22.1)	287 (20.2)	309 (24.3)
60–69	537 (19.9)	295 (20.7)	242 (19.0)
70–79	294 (10.9)	235 (16.5)	59 (4.6)
Mean ± SD	50.2 ± 13.8	52.4 ± 14.3	47.8 ± 12.9
Occupational status			
Worker	1,459 (54.1)	916 (64.3)	543 (42.7)
Housework and/or retired	1,013 (37.6)	395 (27.7)	618 (48.6)
Other (including student)	224 (8.3)	113 (7.9)	111 (8.7)
Duration of LBP			
Acute (<3 months)	526 (19.5)	281 (19.7)	245 (19.3)
Chronic (>3 months)	2,106 (78.1)	1,123 (78.9)	983 (77.3)
Unknown/refused to answer	64 (2.4)	20 (1.4)	44 (3.5)
Disability			
Grade 1[a]	1491 (55.3)	808 (56.7)	683 (53.7)
Grade 2[b]	876 (32.5)	445 (31.3)	431 (33.9)
Grade 3[c]	329 (12.2)	171 (12.0)	158 (12.4)
NRS score (mean ± SE)	5.0 ± 0.0	4.8 ± 0.1	5.2 ± 0.1
Number of pain sites other than LBP (mean ± SE)	1.8 ± 0.0	1.6 ± 0.0	2.1 ± 0.1
EQ5D score (mean ± SE)	0.776 ± 0.003[d]	0.779 ± 0.004	0.772 ± 0.004

LBP Low back pain, *NRS* numeric rating scale, *SE* standard error

[a] LBP without disability for social activity, such as work, school, and housework

[b] LBP with disability for social activity, such as work, school, and housework

[c] LBP with disability leading to absence from social activity, such as work, school, and housework

[d] EQ5D score was significantly lower than that of the total study population (unpaired *t* test, $P < 0.01$)

Table 3 Mean number of pain sites other than LBP, EQ5D score, and NRS score based on the disability of respondents with LBP as their primary pain

Disability (modified GCPS)	*n*	EQ5D score[d] (mean ± SE)	No. of pain sites other than LBP (mean ± SE)	NRS score[e] (mean ± SE)
Grade 1[a]	1,491	0.817 ± 0.003	1.5 ± 0.0	4.2 ± 0.0
Grade 2[b]	876	0.736 ± 0.004	2.3 ± 0.1	5.8 ± 0.1
Grade 3[c]	329	0.694 ± 0.009	2.3 ± 0.1	6.5 ± 0.1

GCPS Graded chronic pain scale, *LBP* low back pain, *NRS* numeric rating scale, *SE* standard error

[a] LBP without disability for social activity, such as work, school, and housework

[b] LBP with disability for social activity, such as work, school, and housework

[c] LBP with disability leading to absence from social activity, such as work, school, and housework

[d] EQ5D score showed a negative correlation with higher disability (Spearman's rank correlation coefficient, –0.371; $P < 0.01$)

[e] NRS score showed a positive correlation with higher disability (Spearman's rank correlation coefficient, 0.418; $P < 0.01$)

from social activity and number of pain sites ≥ 7 had a strong relationship with low HRQoL. Similar trends were observed in both men and women; however, the impacts of absence from social activity and number of pain sites ≥ 7 were stronger in women than in men.

Discussion

In the present study, the 1-month prevalence of LBP was 25.2 % (5060 respondents), which is similar to that reported by Suzukamo and colleagues [15], who noted

Table 4 Mean EQ5D score based on age, sex, and disability of respondents with LBP as the primary pain

Disability		Total (Grades 1 + 2 + 3)			Grade 1[a]			Grade 2[b]			Grade 3[c]		
Sex	Age (years)	*n*	Mean	SE	*n*	Mean	q	*n*	Mean	SE	*n*	Mean	SE
All	20–29	196	0.797	0.009	110	0.822	0.011	69	0.774	0.015	17	0.732	0.043
	30–39	476	0.785	0.006	236	0.828	0.008	173	0.756	0.009	67	0.706	0.021
	40–49	597	0.789	0.005	311	0.830	0.007	213	0.757	0.009	73	0.712	0.017
	50–59	596	0.777	0.006	360	0.817	0.006	172	0.727	0.010	64	0.686	0.021
	60–69	537	0.770	0.006	320	0.814	0.007	155	0.714	0.010	62	0.683	0.021
	70–79	294	0.729	0.008	154	0.782	0.009	94	0.676	0.010	46	0.659	0.026
	Total	2,696	0.776	0.003	1,491	0.817	0.003	876	0.736	0.004	329	0.694	0.009
Male	20–29	80	0.812	0.015	51	0.822	0.017	24	0.781	0.031	5	0.850	0.062
	30–39	229	0.794	0.009	114	0.837	0.011	80	0.772	0.013	35	0.702	0.033
	40–49	298	0.796	0.008	159	0.828	0.009	109	0.757	0.013	30	0.764	0.027
	50–59	287	0.781	0.008	172	0.820	0.009	81	0.725	0.014	34	0.718	0.024
	60–69	295	0.778	0.008	180	0.817	0.009	80	0.722	0.013	35	0.701	0.022
	70–79	235	0.734	0.008	132	0.781	0.009	71	0.666	0.011	32	0.689	0.034
	Total	1,424	0.779	0.004	808	0.817	0.004	445	0.734	0.006	171	0.718	0.013
Female	20–29	116	0.787	0.012	59	0.822	0.015	45	0.770	0.017	12	0.682	0.050
	30–39	247	0.777	0.008	122	0.820	0.011	93	0.743	0.012	32	0.710	0.024
	40–49	299	0.783	0.008	152	0.832	0.010	104	0.756	0.011	43	0.676	0.021
	50–59	309	0.773	0.008	188	0.814	0.008	91	0.730	0.014	30	0.650	0.034
	60–69	242	0.760	0.010	140	0.809	0.011	75	0.706	0.015	27	0.659	0.040
	70–79	59	0.708	0.020	22	0.787	0.034	23	0.704	0.020	14	0.590	0.035
	Total	1272	0.772	0.004	683	0.818	0.005	431	0.738	0.006	158	0.668	0.013

LBP Low back pain, *SE* standard error

[a] LBP without disability for social activity, such as work, school, and housework

[b] LBP with disability for social activity, such as work, school, and housework

[c] LBP with disability leading to absence from social activity, such as work, school, and housework

Table 5 Proportion of LBP with disability, and mean EQ5D and NRS scores based on number of pain sites other than LBP in respondents with LBP as the primary pain

Number of pain sites other than LBP	*n*	EQ5D score[a] (mean ± SE)	LBP with working disability[b] (%)	NRS score[c] (mean ± SE)
0	706	0.813 ± 0.005	35.7	4.1 ± 0.1
1–3	1,582	0.776 ± 0.003	44.0	5.1 ± 0.1
4–6	325	0.729 ± 0.007	59.7	6.1 ± 0.1
≥7	83	0.644 ± 0.014	75.9	7.1 ± 0.2
Total	2,696	0.776 ± 0.002	44.7	5.0 ± 0.0

LBP Low back pain, *NRS* numeric rating scale, *SE* standard error

[a] EQ5D score showed a negative correlation with the number of pain sites other than LBP (Spearman's rank correlation coefficient, −0.256; $P < 0.01$)

[b] Proportion of those with working disability (modified graded chronic pain scale grade 2 or 3 disability) showed a positive correlation with the number of pain sites other than LBP (Spearman's rank correlation coefficient, 0.184; $P < 0.01$)

[c] NRS score showed a positive correlation with the number of pain sites other than LBP (Spearman's rank correlation coefficient, 0.359; $P < 0.01$)

30.6 % as the 1-month prevalence in Japan. Interestingly, of the 5060 respondents, only approximately half (2696 respondents; 13.5 % of all respondents) reported LBP as their primary pain, with the majority reporting chronicity. Recently, LBP has been recognized as a part of widespread musculoskeletal pain. Natvig and colleagues [10] reported that only 25 % of 893 participants who reported LBP during the previous week had localized LBP. In our study, the number of those with LBP as a part of multisite pain was about 6.2 times larger than the number of those with

Table 6 Logistic regression analysis (dependent variable = lowest 20 % of EQ5D scores in total study population)

Variable	Total[a]				Male[b]				Female[b]			
	Adjusted odds	95 % CI		*P* value	Adjusted odds	95 % CI		*P* value	Adjusted odds	95 % CI		*P* value
		Lower	Upper			Lower	Upper			Lower	Upper	
Modified GCPS												
Grade 1	1.000				1.000				1.000			
Grade 2	2.930	2.393	3.589	<0.001	3.151	2.377	4.177	<0.001	2.750	2.052	3.686	<0.001
Grade 3	4.580	3.488	6.013	0.001	3.789	2.603	5.517	<0.001	5.642	3.780	8.420	<0.001
No. of pain sites other than LBP												
0	1.000				1.000				1.000			
1–3	1.420	1.128	1.786	0.003	1.173	0.873	1.576	0.290	1.850	1.275	2.685	0.001
4–6	2.367	1.733	3.232	<0.001	2.146	1.365	3.375	0.001	2.856	1.816	4.492	<0.001
≧7	6.124	3.541	10.589	<0.001	4.579	2.010	10.432	<0.001	8.426	3.970	17.882	<0.001
Sex												
F/M	1.044	0.868	1.256	0.644								
Age (years)												
<60	1.000				1.000					1.000		
≧60	1.545	1.271	1.879	<0.001	1.598	1.234	2.068	<0.001	1.485	1.097	2.011	0.010
NRS score												
<7	1.000				1.000					1.000		
≧7	1.883	1.541	2.300	<0.001	2.129	1.608	2.820	<0.001	1.650	1.238	2.200	0.001

CI Confidence interval, *F* female, *GCPS* graded chronic pain scale, *LBP* low back pain, *M* male, *NRS* numeric rating scale

[a] Multivariate analysis adjusted by modified GCPS, number of pain sites other than LBP, sex, age, and NRS score

[b] Multivariate analysis adjusted by modified GCPS, number of pain sites other than LBP, age, and NRS score

localized LBP. Previous studies [9, 10] have reported that many LBP respondents have pain elsewhere, which could be the primary reason for their disability. Therefore, we focused on LBP respondents reporting LBP as their primary pain for further analyses in this study.

In the present study, the mean EQ-5D score of those with LBP as their primary pain was 0.776 (SE, 0.003), which was significantly lower than that of the total study population [0.850 (SE, 0.001); $P < 0.01$], and slightly lower than the average score of patients with stage 5 chronic kidney disease (CKD) in Japan (0.798; 95 % CI, 0.757–0.839) [16]. Since stage 5 CKD represents established kidney failure, the similar HRQoL obtained in the present study indicates that the HRQoL of those who suffer from LBP could be as low as, or even lower than, those who are candidates for hemodialysis.

Generally, lower HRQoL is reported with higher disability in LBP patients [8, 17, 18]. Kovacs and colleagues revealed a negative correlation between the Rolland Morris Disability Questionnaire and the EQ-5D in LBP [8, 18]. In the present study, we used the GCPS [12], a well validated scale for assessing LBP disability, with minor revision. The revision was made to focus on disability and absence from social activity because the impacts of these disabilities on HRQoL have not been well examined. In our study, there was a negative correlation between disability and HRQoL, as in previous studies [8, 17, 18]. The differences in the mean EQ-5D scores between those with and those without disability and absence were 0.08 and 0.04, respectively. Interestingly, the differences were similar to the minimal clinically important difference reported in previous studies (0.033–0.074) [19, 20]. Collectively, these data suggest that the presence of disability for social activity and its severity regarding absence might have a significant meaning for those who suffer from LBP. Therefore, improvement of these disabilities might represent a clinically important difference, which needs further investigation.

In our study, HRQoL decreased as the number of pain sites increased, thus showing a negative correlation, whereas the proportion of disability and pain intensity increased as the pain sites increased. Kamaleri and colleagues [9] revealed that single-site pain did not have a large impact on physical fitness, feelings, or daily and social activities, and that functional problems increased markedly, in an almost linear manner, with increase in number of pain sites. From another study, the widest variation in health-related functioning, such as the items on the short form-36, was observed by the number of pain sites, with lower function seen with increase in number of pain sites [21]. LBP patients also have lower general health, poorer function, and poorer long-term work disability when their LBP is accompanied by multisite pain [10, 22, 23]. Our findings are consistent with those of previous reports, showing a similar relationship among pain intensity, disability, HRQoL, and number of pain sites in LBP responders. The reason why the majority of those

with LBP as their primary pain also reported multisite pain could be the generalized hyperalgesia known to exist in LBP patients [24]. Compared with healthy control subjects, LBP patients exhibit significantly lower pressure pain thresholds at all sites [25, 26]. The continuous nociceptive input might initiate central sensitization [27], which could develop widespread pain in those with LBP as their primary pain [24, 27].

In multivariate analyses, after adjusting for all the variables, modified GCPS grade, number of pain sites, age ≥60 years, and pain intensity were found to be associated with low HRQoL. Among these variables, disability with absence from social activity and ≥7 pain sites showed a stronger association than pain intensity (NRS score ≥7) and age ≥60 years. A similar tendency was seen in both men and women, highlighting the importance of multisite pain and disability in those who suffer from LBP. Although our study had limitations (due to its cross-sectional design), we believe the strong relationships seen in our study are noteworthy. Based on our results, occupational management [28, 29] focusing on returning to work, and management of multisite pain might have a more significant effect on HRQoL improvement than the management of pain itself in those who suffer from LBP. Further study is necessary to evaluate the effects of such management.

The strengths of our study include the large size of the population sample used to estimate the prevalence of those with LBP as their primary pain, and the magnitude of the associations among disability, pain intensity, number of pain sites, and HRQoL without any missing data. Some results support the validity of the PACE survey. First, the mean EQ-5D score of the PACE survey was similar to that found in a well-designed general population study (0.835) [30]. Second, the ceiling effect of the EQ-5D seen in the total study population also was similar to that reported in previous studies (42.5–47.0 %) [30–32]. Third, the percentage of those with LBP was similar to that reported previously in Japan [15]. Fourth, the percentage of workers in the total study population (52.8 %) was similar to that announced by the Japanese Ministry of Internal Affairs and Communications in 2009 (56.9 %) [11].

Some limitations in our study are notable, however. First, the selection bias due to the nature of an Internet survey needs to be addressed [33]. Although the study was conducted nationwide, using one of the largest domestic Internet survey companies, the volunteers from whom our sample was drawn were overrepresentative of people living in large cities, compared with the general population. Since LBP prevalence has geographic differences, with higher rates in urban populations than rural populations [34], caution is needed when interpreting the results of this study. Second, those who participate as Internet research volunteers may differ from the general population, and even from general Internet users. These potential differences could have affected the prevalence of LBP. Third, regarding the type of questionnaire, although a previous study reported that a Web-based questionnaire had adequate reliability compared with the paper-and-pencil version, even for older rural women [35], the mode of administration could affect the nature and rate of response [36]. Fourth, because this was a cross-sectional study, inferences cannot be drawn about causality.

In an Internet-based survey conducted in the United States, more than 27 000 individuals responded with a high response rate (75.7 %). The authors used a nationally representative Web-enabled panel of households that were recruited using a combination of random-digit dialing, landline-telephone recruiting, and address-based sampling [37]. Recruited households that did not have Internet access were provided free access via WebTV. Unlike other Internet-based surveys, the Internet-enabled panel used in the study was not limited to individuals with Internet access, and the sampling methodology was designed to ensure that the demographic characteristics of the panel were similar to those of the United States population. The methods used in this United States study maintain the representativeness of the study, while utilizing the advantages of Internet-based surveys for collecting a large amount of data. Such methodologic improvement might be necessary in our future studies.

Conclusion

Only approximately half of the LBP respondents reported LBP as their primary pain; among them, HRQoL decreased with higher disability and an increase in the number of pain sites. The presence of ≥7 pain sites and disability resulting in absence from social activity were strongly associated with low HRQoL. Occupational management focusing on return to work and management of multisite pain may have a more significant effect on HRQoL improvement than the management of pain itself in individuals with LBP. Further research should focus on the effectiveness of such management in LBP respondents.

Acknowledgments This study was supported by the dissemination project on the 13 fields of occupational injuries and illness of the Japan Labor Health and Welfare Organization. All investigations were conducted in conformity with ethical principles of research, and informed consent was obtained for participation in the study.

Conflict of interest None.

References

1. Jacob T. Low back pain incident episodes: a community-based study. Spine J. 2006;6:306–10.

2. Maniadakis N, Gray A. The economic burden of back pain in the UK. Pain. 2000;84:95–103.
3. Derebery VJ, Giang GM, Saracino G, Fogarty WT. Evaluation of the impact of a low back pain educational intervention on physicians' practice patterns and patients' outcomes. J Occup Environ Med. 2002;44:977–84.
4. Airaksinen O, Brox JI, Cedraschi C, Hildebrandt J, Klaber-Moffett J, Kovacs F, et al. Chapter 4. European guidelines for the management of chronic nonspecific low back pain. Eur Spine J. 2006;15(Suppl 2):S192–300.
5. van Tulder M, Koes B, Bombardier C. Low back pain. Best Pract Res Clin Rheumatol. 2002;16:761–75.
6. Dionne CE, Dunn KM, Croft PR, Nachemson AL, Buchbinder R, Walker BF, et al. A consensus approach toward the standardization of back pain definitions for use in prevalence studies. Spine (Phila Pa 1976). 2008;33:95–103.
7. Leboeuf-Yde C, Lauritsen JM. The prevalence of low back pain in the literature. A structured review of 26 Nordic studies from 1954 to 1993. Spine (Phila Pa 1976). 1995;20:2112–8.
8. Kovacs FM, Abraira V, Zamora J, Teresa Gil del Real M, Llobera J, Fernandez C, et al. Correlation between pain, disability, and quality of life in patients with common low back pain. Spine (Phila Pa 1976). 2004;29:206–10.
9. Kamaleri Y, Natvig B, Ihlebaek CM, Bruusgaard D, et al. Localized or widespread musculoskeletal pain: does it matter? Pain. 2008;138:41–6.
10. Natvig B, Bruusgaard D, Eriksen W. Localized low back pain and low back pain as part of widespread musculoskeletal pain: two different disorders? A cross-sectional population study. J Rehabil Med. 2001;33:21–5.
11. Japanese Ministry of Internal Affairs and Communications. Statistics Bureau, Director-General for Policy Planning (Statistical Standards) and Statistical Research and Training Institute. http://www.stat.go.jp/data/jinsui/2007np/index.htm. Accessed Mar 16, 2012; (in Japanese).
12. Von Korff M, Ormel J, Keefe FJ, Dworkin SF. Grading the severity of chronic pain. Pain. 1992;50:133–49.
13. Tsuchiya A, Ikeda S, Ikegami N, Nishimura S, Sakai I, Fukuda T, et al. Estimating an EQ-5D population value set: the case of Japan. Health Econ. 2002;11:341–53.
14. EuroQol–a new facility for the measurement of health-related quality of life. The EuroQol Group. Health Policy. 1990;16:199–208.
15. Suzukamo Y, Takahashi N, Konno S, Kikuchi S, Fukuhara S. Outcome study of low back pain. Pharma Medica. 2007;25:9–12 (in Japanese).
16. Tajima R, Kondo M, Kai H, Saito C, Okada M, Takahashi H, et al. Measurement of health-related quality of life in patients with chronic kidney disease in Japan with EuroQol (EQ-5D). Clin Exp Nephrol. 2010;14:340–8.
17. Garratt AM, Klaber Moffett J, Farrin AJ. Responsiveness of generic and specific measures of health outcome in low back pain. Spine (Phila Pa 1976). 2001;26:71–7; (discussion 7).
18. Kovacs FM, Abraira V, Zamora J, Fernandez C; Spanish Back Pain Research Network. The transition from acute to subacute and chronic low back pain: a study based on determinants of quality of life and prediction of chronic disability. Spine (Phila Pa 1976). 2005;30:1786–92.
19. Burstrom K, Johannesson M, Rehnberg C. Deteriorating health status in Stockholm 1998–2002: results from repeated population surveys using the EQ-5D. Qual Life Res. 2007;16:1547–53.
20. Walters SJ, Brazier JE. Comparison of the minimally important difference for two health state utility measures: EQ-5D and SF-6D. Qual Life Res. 2005;14:1523–32.
21. Saastamoinen P, Leino-Arjas P, Laaksonen M, Martikainen P, Lahelma E. Pain and health related functioning among employees. J Epidemiol Community Health. 2006;60:793–8.
22. Natvig B, Eriksen W, Bruusgaard D. Low back pain as a predictor of long-term work disability. Scand J Public Health. 2002;30:288–92.
23. Leveille SG, Bean J, Ngo L, McMullen W, Guralnik JM. The pathway from musculoskeletal pain to mobility difficulty in older disabled women. Pain. 2007;128:69–77.
24. Kindler LL, Bennett RM, Jones KD. Central sensitivity syndromes: mounting pathophysiologic evidence to link fibromyalgia with other common chronic pain disorders. Pain Manag Nurs. 2011;12:15–24.
25. O'Neill S, Manniche C, Graven-Nielsen T, Arendt-Nielsen L. Generalized deep-tissue hyperalgesia in patients with chronic low-back pain. Eur J Pain. 2007;11:415–20.
26. Laursen BS, Bajaj P, Olesen AS, Delmar C, Arendt-Nielsen L. Health related quality of life and quantitative pain measurement in females with chronic non-malignant pain. Eur J Pain. 2005;9:267–75.
27. Woolf CJ. Central sensitization: implications for the diagnosis and treatment of pain. Pain. 2011;152:S2–15.
28. Loisel P, Abenhaim L, Durand P, Esdaile JM, Suissa S, Gosselin L, et al. A population-based, randomized clinical trial on back pain management. Spine (Phila Pa 1976). 1997;22:2911–8.
29. Lemstra M, Olszynski WP. The effectiveness of standard care, early intervention, and occupational management in worker's compensation claims. Spine (Phila Pa 1976). 2003;28:299–304.
30. Saarni SI, Harkanen T, Sintonen H, Suvisaari J, Koskinen S, Aromaa A, et al. The impact of 29 chronic conditions on health-related quality of life: a general population survey in Finland using 15D and EQ-5D. Qual Life Res. 2006;15:1403–14.
31. Burstrom K, Johannesson M, Diderichsen F. Swedish population health-related quality of life results using the EQ-5D. Qual Life Res. 2001;10:621–35.
32. Nordlund A, Ekberg K, Kristenson M. EQ-5D in a general population survey–a description of the most commonly reported EQ-5D health states using the SF-36. Qual Life Res. 2005;14:1099–109.
33. Eysenbach G, Wyatt J. Using the Internet for surveys and health research. J Med Internet Res. 2002;4:E13.
34. Volinn E. The epidemiology of low back pain in the rest of the world. A review of surveys in low- and middle-income countries. Spine (Phila Pa 1976). 1997;22:1747–54.
35. Boeckner LS, Pullen CH, Walker SN, Abbott GW, Block T. Use and reliability of the World Wide Web version of the Block Health Habits and History Questionnaire with older rural women. J Nutr Educ Behav. 2002;34(Suppl 1):S20–4.
36. Turner CF, Ku L, Rogers SM, Lindberg LD, Pleck JH, Sonenstein FL. Adolescent sexual behavior, drug use, and violence: increased reporting with computer survey technology. Science. 1998;280:867–73.
37. Johannes CB, Le TK, Zhou X, Johnston JA, Dworkin RH. The prevalence of chronic pain in United States adults: results of an Internet-based survey. J Pain. 2010;11:1230–9.

J Orthop Sci (2013) 18:14–21
DOI 10.1007/s00776-012-0304-y

ORIGINAL ARTICLE

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

Katsushi Takeshita · Noboru Hosono · Yoshiharu Kawaguchi · Kyoichi Hasegawa · Tatsuya Isomura · Yasushi Oshima · Takashi Ono · Masahito Oshina · Takenori Oda · So Kato · Kazuo Yonenobu

Received: 5 July 2012 / Accepted: 16 August 2012 / Published online: 4 September 2012

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

Electronic supplementary material The online version of this article (doi:10.1007/s00776-012-0304-y) contains supplementary material, which is available to authorized users.

K. Takeshita (✉) · Y. Oshima · T. Ono · S. Kato
Department of Orthopaedic Surgery, Faculty of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-8655, Japan
e-mail: dtstake@coral.ocn.ne.jp

N. Hosono
Orthopaedic Surgery, Osaka Kosei Nenkin Hospital, Osaka, Japan

Y. Kawaguchi
Orthopaedic Surgery, University of Toyama, Toyama, Japan

K. Hasegawa
Orthopaedic Surgery, Sapporo Orthopaedics and Cardiovascular Hospital, Sapporo, Japan

T. Isomura
Clinical Study Support, Inc., Nagoya, Japan

M. Oshina
Orthopaedic Surgery, Yokohama Rosai Hospital, Kanagawa, Japan

T. Oda
Orthopaedic Surgery, Osaka Rosai Hospital, Sakai, Japan

K. Yonenobu
Orthopaedic Surgery, National Hospital Organization Osaka Minami Medical Center, Osaka, Japan

Introduction

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

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

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

Materials and methods

Translation of the NDI into Japanese

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

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

Participants

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

Data collection

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

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

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

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

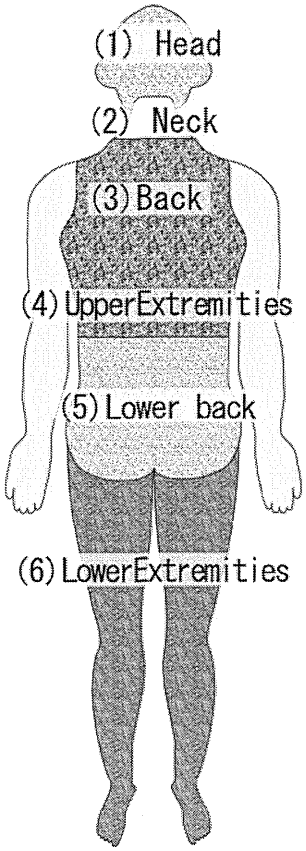

Fig. 1 The body part figure used for the question about the intensity of the pain and numbness

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

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

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

Table 1 Patient characteristics ($n = 130$)

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

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

SD standard deviation, *BMI* body mass index

Statistical analysis

Internal consistency, criterion-related validity and discriminative validity

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

Table 2 The outcomes of the first survey

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

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

Reliability and responsiveness

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

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