

DOI: 10.21767/2471-982X.100017

Validation of Pain Severity Assessment using the PainDETECT Questionnaire

Hiroaki Abe¹,
Masahiko Sumitani^{2*},
Yoshitaka Matsubayashi³,
Rikuhei Tsuchida¹,
Yasushi Oshima³,
Katsushi Takeshita⁴ and
Yoshitsugu Yamada¹

Abstract

Background: The PainDETECT Questionnaire (PD-Q) is a screening tool for Neuropathic Pain (NeP). A cut-off value of ≥ 13 indicates the possibility of NeP components. The PD-Q score seems to reliably distinguish the severity of NeP; however, it has not yet been validated whether changes of the PD-Q score can follow changes of pain severity assessed using an 11-point Numerical Rating Scale (NRS).

Methods: Sixty patients diagnosed with NeP answered the PD-Q, NRS, and Neuropathic Pain Symptom Inventory (NPSI). We analyzed correlations among them by using the Pearson correlation test. Another 49 patients with NeP answered the PD-Q and NRS twice, with the second survey being conducted 8 weeks after the first survey. Correlations were analyzed between the %decrease of PD-Q and NRS scores. In both experiments, the participants were divided into two groups according to the PD-Q score (cut-off value of 13). For these groups, we also analyzed the correlations.

Results: The PD-Q showed fair to moderate correlation with the NRS and NPSI. The PD-Q could linearly track changes of the NRS. Analyses of subsets revealed that patients with PD-Q scores ≥ 13 showed similar correlations, whereas those with PD-Q scores <13 did not.

Conclusion: Despite the limited number of patients included, our findings suggest that the PD-Q can be suitable for assessing and tracking pain severity in patients with NeP at least in common clinical settings. Sufficient attention should be paid when using the PD-Q as an outcome measure for patients with a low PD-Q score.

Keywords: Neuropathic pain; painDETECT; Screening; Severity of pain; Validation

- 1 Department of Anesthesiology and Pain Relief Center, The University of Tokyo Hospital, Japan
- 2 Department of Pain and Palliative Medicine, The University of Tokyo Hospital, Japan
- 3 Department of Orthopaedic Surgery and Spinal Surgery, The University of Tokyo Hospital, Japan
- 4 Department of Orthopaedic Surgery, Jichi Medical University, Japan

Corresponding author:

Masahiko Sumitani, MD, PhD

✉ sumitanim-ane@h.u-tokyo.ac.jp

Department of Pain and Palliative Medicine,
The University of Tokyo Hospital, Hongo 7-3-1,
Bunkyo, Tokyo 113-0033, Japan.

Tel: +81-3-3815-5411

Citation: Abe H, Sumitani M, Matsubayashi Y, Tsuchida R, Oshima Y, et al. (2017) Validation of Pain Severity Assessment using the PainDETECT Questionnaire. *Int J Anesth Pain Med.* Vol. 3 No. 1:3

Received: August 20, 2017; **Accepted:** September 09, 2017; **Published:** September 16, 2017

Introduction

The International Association for the Study of Pain (IASP) defines Neuropathic Pain (NeP) as “pain arising as a direct consequence of a lesion or disease affecting the somatosensory system” [1]. NeP has certain characteristics that set it apart from nociceptive pain. For example, patients with nociceptive pain caused by cancer consistently characterize their pain as heavy, lacerating, and suffocating, while patients with NeP tend to describe their pain as aching, throbbing, numb, and miserable [2]. Further, such quality of pain can indicate response to therapy. We previously demonstrated that the two categories of NeP characteristics (superficial-pain descriptions [burning, tingling, piercing, etc.] and deep-somatic descriptions [squeezing, cramp-like, twisting, etc.]

are differently alleviated by mirror visual feedback treatment [3]. Thus, the quality of pain is useful for interpreting the underlying pathophysiological mechanism(s) of pain.

A variety of measurements and questionnaires are used to evaluate pain as objectively as possible. NeP does not possess distinct pathognomonic features, and hence, screening tools are needed that use the most characteristic symptoms and signs of NeP for proper identification and treatment of patients. Currently, several simple and reliable questionnaires are available

for screening NeP components [4], which support the earlier detection and appropriate treatment of this disease. Among these questionnaires, the PainDETECT Questionnaire (PD-Q), developed by German pain researchers in 2004, can successfully perform subgrouping of patients to classify the profile of individual pain-related sensory abnormalities [5,6]. It has been translated and validated in multiple languages, including Japanese [7]. These translated PD-Qs generally demonstrate fair to good criterion-related validity with an 11-point numerical rating scale (NRS) for pain intensity, excellent internal consistency, and high reliability with significance for patients with NeP. Many drug studies have reported the change of the PD-Q symptom intensity and its scores over time. Some studies have reported the PD-Q score and used it to identify patients with NeP components at baseline [8-11]. Other studies have used the PD-Q to assess the response of NeP components to therapy [12,13]. These studies showed that the PD-Q score significantly improved at the end of the treatment period. The PD-Q seems to reliably distinguish the severity of pain in patients with NeP [14]; however, it has not yet been validated whether the changes of the PD-Q score can follow changes of pain severity assessed using the NRS in both the high and low PD-Q score subsets. In fact, one of the largest longitudinal observational studies on a drug treatment demonstrated significant improvement in NRS scores but not in the PD-Q scores [15]. In the present study, we examined whether the PD-Q score reflected pain intensity and could be used to track the course of pain symptoms over time in both patients with NeP components (i.e., PD-Q score ≥ 13) and without NeP components (i.e., PD-Q score < 13).

Materials and Methods

Experiment 1

Subjects: The study protocol was approved by the institutional review board of the University of Tokyo Hospital and adhered to the guidelines of the Helsinki Declaration.

Sixty patients referred to the outpatient clinic of the Department of Anesthesiology and Pain Relief Center at The University of Tokyo Hospital was eligible for participation in this study. The inclusion criteria were as follows: (i) diagnosed with NeP by their attending pain specialist as per guidelines established by the IASP Neuropathic Pain Special-Interest-Group [16]; (ii) mean pain intensity in the past month (recorded at inclusion) of ≥ 3 on an 11-point NRS (0 = no pain; 10 = worst possible pain); (iii) pain duration of ≥ 3 months; and (iv) age ≥ 20 years. The exclusion criteria were comorbid psychiatric disorders such as schizophrenia, personality disorders, and other psychotic disorders as defined by the ICD-10. Patients were enrolled after they provided informed consent. They were divided into two groups according to the PD-Q score; patients with a low PD-Q score (< 13) indicating nociceptive pain and those with a high PD-Q score (≥ 13) indicating possible and likely NeP components.

The patients were asked to complete a set of questionnaires including the PD-Q Japanese version, a three-type NRS on pain intensity, the Japanese version of the short-form McGill Pain Questionnaire (SF-MPQ), the Medical Outcomes Study 36-Item

Short-Form Health Survey (SF-36) for assessing their health-related quality of life (QOL), and the Neuropathic Pain Symptoms Inventory (NPSI) Japanese version for specifically assessing the severity of NeP [17-23]. The PD-Q identifies and rates seven pathological pain qualities: burning, tingling or prickling sensations, tactile and thermal allodynia, electric shock-like sensations, numbness, and pressure-evoked pain sensation. Moreover, the PD-Q evaluates the presence or absence of gradation of pain, pain course pattern, and the presence or absence of radiating pain. Pain intensity was assessed using a three-type NRS in which the patients were asked to grade the current pain, the average pain in the past 4 weeks, and the worst pain in the past 4 weeks on an 11-point NRS. The SF-MPQ comprises two dimensions of pain (i.e., sensory and affective). The total score of these dimensions of the SF-MPQ is generally useful for assessing pain severity in relation with the activities of daily living; however, the SF-MPQ tends to be less sensitive than the simpler pain ratings (e.g., NRS). The NPSI specifically assesses NeP severity, and the psychometric validation of the Japanese version of the NPSI has already been performed [22]. The NPSI comprises four main components (i.e., spontaneous pain, paroxysmal pain, evoked pain, and sensation), which encompass 12 questions. The NPSI score is calculated by adding the scores of these four components, with a higher score indicating more severe NeP. The SF-36 consists of eight subscales, namely physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. We have previously reported that the PD-Q and SF-36 scores demonstrate similar trends: patients with NeP had lower physical and mental functioning than did those with nociceptive pain [7]. For analyses, we calculated two summed scores on the basis of these subscales: the physical component score (PCS) and the mental component score (MCS). Lower PCS and MCS indicate poorer health-related QOL. Each has the same mean and standard deviation (50 and 10, respectively) in a normal population.

To determine criterion-related validity, we calculated the Pearson correlation coefficient between the PD-Q score and three-type NRS score, the NPSI score, the SF-MPQ score, PCS of SF-36, and MCS of SF-36. The following ranges are 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 0.2-0.0 (poor) [24]. Demographic data of the two patient groups were analyzed using the Mann-Whitney test and Chi-square test as appropriate. All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA).

Experiment 2

Subjects: A different patient cohort with NeP (n=49) was eligible for participation after they provided informed consent. The inclusion and exclusion criteria were identical to those for Experiment 1. These patients were also divided into two groups: patients with a low PD-Q score (< 13) and patients with a high PD-Q score (≥ 13). In Experiment 2, we used a simple set of the PD-Q and three-type NRS (i.e., current pain, average pain in the past 4 weeks, and worst pain in the past 4 weeks), because previous studies on drug treatment used these parameters as the primary

and secondary endpoints [8-13,15]. The patients were asked to complete them twice. The second survey was administered to the patients at around 8 weeks after the first survey. The attending physicians prescribed medicines at their discretion for treating the patients through the period between the first and second surveys. Decreases in the three-type NRS and PD-Q scores from the first survey to the second survey were expressed in percentage terms. To validate whether the %decrease of the PD-Q score could track that of the NRS score, we calculated the Pearson correlation coefficient between the %decreases of the PD-Q score and three-type NRS score. Demographic data of the two patient groups were analyzed using the Mann-Whitney test and Chi-square test as appropriate. All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp.).

Results

Experiment 1

The specific cause of NeP in the patients were brachial plexus injury (n=12), radiculopathy (n=11); spinal cord injury (n=10); post-herpetic neuralgia (n=11); diabetic, alcoholic, or chemotherapy-induced polyneuropathy (n=6); post-amputation phantom limb pain (n=5); complex regional pain syndrome (n=2); carpal tunnel syndrome (n=1); trigeminal nerve injury pain (n=1); and thalamic pain (n=1). Forty-three patients had a high PD-Q score (≥ 13), and 17 had a low PD-Q score. The demographic data of the two groups were comparable (**Table 1**). Despite the difference in the PD-Q scores, the three-type NRS, SF-MPQ, and SF-36 subscale scores were comparable between these two patient groups. The difference in the NPSI scores reached significance ($p=0.02$). Regarding criterion-related validity of the whole dataset of patients with NeP (n=60), the total PD-Q score exhibited statistically significant correlations with current pain ($r=0.29$, $p=0.03$), worst pain in the past 4 weeks ($r=0.36$, $p=0.005$), average pain in the past 4 weeks ($r=0.33$, $p=0.009$), the total NPSI score ($r=0.69$, $p<0.001$), and the total SF-MPQ score ($r=0.63$,

$p<0.001$). The correlation between the PD-Q score and the SF-36 subscale scores (PCS and MCS) did not reach significance ($p=0.55$ and 0.15 , respectively). In the subset of patients (n=43) with a high PD-Q score (≥ 13) that indicates neuropathic components, the same parameters, except for current pain ($p=0.38$), were significantly correlated with the PD-Q score (i.e., worst pain in the past 4 weeks, $r=0.36$, $p=0.02$; average pain in the past 4 weeks, $r=0.32$, $p=0.04$; NPSI, $r=0.53$, $p=0.0003$; SF-MPQ, $r=0.54$, $p=0.0003$). In addition, correlations between the PD-Q score and the SF-36 subscale scores (PCS and MCS) were not observed ($p=0.77$ and 0.20 , respectively). In the other subset of patients (n=17) with a low PD-Q score (<13), no parameters correlated with the PD-Q score (current pain, $p=0.41$; worst pain in the past 4 weeks, $p=0.77$; average pain in the past 4 weeks, $p=0.79$; NPSI, $p=0.16$; SF-MPQ, $p=0.89$; SF-36-PCS, $p=0.61$; SF-36-MCS, $p=0.24$).

Experiment 2

The specific causes of NeP in the patients were brachial plexus injury (n=15); radiculopathy (n=11); spinal cord injury (n=5); post-herpetic neuralgia (n=8); diabetic, alcoholic, or chemotherapy-induced polyneuropathy (n=3); post-amputation phantom limb pain (n=3); carpal tunnel syndrome (n=2); trigeminal nerve injury pain (n=1); and thalamic pain (n=1). Thirty-five patients had a high PD-Q score (≥ 13), and 14 had a low PD-Q score. The demographic data of the two groups were comparable (**Table 2**). Despite the significant difference in the PD-Q scores, the three-type NRS scores were not different between these two patient groups.

Decrease of the PD-Q score in percentage terms was significantly associated with %decreases of current pain ($r=0.31$, $p=0.03$) and average pain in the past 4 weeks ($r=0.33$, $p=0.02$), but showed a tendency to be associated with a %decrease of worst pain in the past 4 weeks ($r=0.28$, $p=0.052$) in all the patients with NeP (n=49). These correlations were also observed in the subset of 35 patients with a high PD-Q score (≥ 13) (current pain, $r=0.38$, $p=0.03$; average pain in the past 4 weeks, $r=0.53$, $p=0.001$; worst pain in the past 4 weeks, $r=0.28$, $p=0.098$). However, the

Table 1 Demographic data of patients with neuropathic pain who participated in experiment.

	All patients with neuropathic pain	Patients with neuropathic pain and PD-Q score ≥ 13	Patients with neuropathic pain and PD-Q score <13	p-value*	
Age	59.3 \pm 15.2	57.3 \pm 15.1	64.2 \pm 14.8	0.13	
Sex (male/female)	39/21	29/14	10/7	0.65	
Height (cm)	163.7 \pm 9.9	164.3 \pm 9.4	162.0 \pm 11.1	0.99	
Body weight (kg)	63.8 \pm 17.5	66.2 \pm 17.5	57.7 \pm 16.3	0.23	
PD-Q	18.2 \pm 6.2	21.2 \pm 4.5	10.6 \pm 1.7	0.001	
NRS	Current pain	6.5 \pm 2.3	6.9 \pm 2.0	5.5 \pm 2.7	0.62
	Worst pain in the past 4 weeks	8.3 \pm 1.7	8.5 \pm 1.6	7.6 \pm 1.6	0.33
	Average pain in the past 4 weeks	6.7 \pm 2.0	7.0 \pm 1.9	6.0 \pm 2.2	0.24
NPSI	4.2 \pm 2.2	5.0 \pm 1.9	2.4 \pm 1.6	0.02	
SF-MPQ	17.7 \pm 8.9	20.3 \pm 8.6	11.2 \pm 6.1	0.23	
SF-36	Physical component score	27.3 \pm 16.5	26.4 \pm 16.1	29.5 \pm 17.7	0.95
	Mental component score	41.3 \pm 11.9	40.2 \pm 11.2	44.1 \pm 13.4	0.95

Data were presented as mean \pm standard deviation.

PD-Q = painDETECT questionnaire; NRS = numerical rating scale (an 11-point numerical rating scale on pain intensity); NPSI = Neuropathic Pain Symptom Inventory; SF-MPQ = McGill Pain Questionnaire short-form; SF-36 = Medical Outcomes Study 36-item Short-Form Health Survey.

Table 2 Demographic data of patients with neuropathic pain who participated in experiment 2.

	All patients with neuropathic pain	Patients with neuropathic pain and PD-Q score ≥ 13	Patients with neuropathic pain and PD-Q score < 13	<i>p</i> -value*	
Age	58.2 \pm 15.1	56.0 \pm 13.2	63.7 \pm 18.4	0.09	
Sex (male/female)	35/14	26/9	09/5	0.49	
Height (cm)	164.5 \pm 8.9	165.9 \pm 8.9	160.8 \pm 8.2	0.05	
Body weight (kg)	62.2 \pm 13.7	63.6 \pm 14.8	58.8 \pm 9.9	0.25	
PD-Q	18.5 \pm 7.4	21.8 \pm 5.8	10.1 \pm 2.2	<0.001	
NRS	Current pain	5.7 \pm 2.1	5.9 \pm 1.9	5.4 \pm 2.5	0.52
	Worst pain in the past 4 weeks	8.2 \pm 1.6	8.3 \pm 1.6	8.0 \pm 1.6	0.52
	Average pain in the past 4 weeks	6.1 \pm 1.7	6.1 \pm 1.7	6.0 \pm 1.8	0.7

Data were presented as mean \pm standard deviation.
 PD-Q = painDETECT questionnaire; NRS = numerical rating scale (an 11-point numerical rating scale on pain intensity).
 *Data of the two subsets of patients were compared using the Mann-Whitney test or Chi-square test.

other subset of 14 patients with a low PD-Q score (<13) did not demonstrate any correlations among the PD-Q and three-type NRS scores (current pain, $p=0.14$; average pain in the past 4 weeks, $p=0.88$; and worst pain in the past 4 weeks, $p=0.21$).

Discussion

The results of the present study revealed at least fair to moderate validity for assessing NeP severity by using the PD-Q. Our findings were consistent with those of a previous study in which the patients with NeP were stratified into three pain severity groups according to the Brief Pain Inventory Short-Form (i.e., mild, moderate, and severe), and the average PD-Q scores of the three groups increased in a step-wise manner [14]. Further, the present study revealed that changes of the PD-Q score can follow changes of pain severity assessed using the NRS over time. Therefore, we can conclude that the PD-Q score reliably reflects the severity of pain in patients with NeP.

Analyzing subsets of patients with NeP illustrated the importance of paying attention to the PD-Q score when evaluating NeP severity by using the PD-Q. Patients with a high PD-Q score (≥ 13) demonstrated the validity of severity assessment using the PD-Q, and their PD-Q scores tracked the course of pain symptoms over time. However, a small fraction of patients who had a low PD-Q score (<13) did not demonstrate such validity. Previous longitudinal studies on drug treatment used the PD-Q score as one of the inclusion criteria (i.e., score ≥ 13) to identify patients with NeP components [8-11], and these studies successfully revealed that the experimental drug showed significant improvements in the NRS as well as the PD-Q scores. Different from these studies, a small prospective open-label study [13] used the PD-Q in addition to the NRS to evaluate cancer pain severity. That study included 46% patients without NeP components on the basis of their PD-Q scores (i.e., <13). The experimental drug improved the NRS scores significantly, but the results regarding the PD-Q scores were not reported. Another open-label study on patients with NeP [15] used the PD-Q not only to identify NeP components (consequently, 18.3% of the patients had low PD-Q scores [<13]) but also to evaluate its severity. However, that study also did not present the results of the PD-Q scores over time, because completion of the PD-Q was optional in that study. To our best knowledge, no data are available to suggest that the

PD-Q can appropriately reflect the severity of pain in patients with a low PD-Q score (<13). At least, our present findings indicated that the PD-Q in patients with a low PD-Q score should be applied cautiously when strictly assessing and tracking pain severity in clinical trials. This might be possibly supported by a previous finding that the PD-Q score was less sensitive to reflect pain severity and the analgesic effect of an experimental drug in patients with a PD-Q score between 13 and 18 than in those with a much higher PD-Q score (≥ 19) [10]. Moreover, supporting evidence comes from another previous finding that patients with a much higher PD-Q score (≥ 19) showed a larger effect size of clinically meaningful improvements in all SF-12 subscale scores used for assessing an experimental drug, but patients with a PD-Q score between 13 and 18 showed improvements in limited SF-12 subscale scores [8]. We previously reported that a higher PD-Q score reflects stronger impairments of patients' mental and physical states in both patients with neuropathic and nociceptive pain [7]. However, in our present study, the PD-Q score showed such tendency, but did not linearly correlate with the SF-36 subscale scores not only in patients with a low PD-Q score (<13) but also in those with a high PD-Q score (≥ 13). Previous epidemiological studies have revealed that patients with a higher PD-Q score demonstrated worse health-related QOL, but these studies did not necessarily confirm the linear correlation between the PD-Q score and impairments of the health-related QOL [25-27]. Therefore, the PD-Q should not serve as a surrogate for assessing the health-related QOL in some circumstances requiring its strict assessment, such as in clinical trials.

The PD-Q is an easy-to-administer patient self-reported instrument for detecting NeP components without the necessity of limited clinical examinations. Our findings suggest that the PD-Q can be suitable for assessing and tracking pain severity in patients with NeP at least in common clinical settings. However, clinicians and clinical researchers should pay sufficient attention when using the PD-Q as an outcome measure in clinical trials. In particular, it would not be accurate to use the PD-Q score to assess the pain severity among patients with NeP and a low PD-Q score (<13). This study was retrospectively analyzed for exploratory purposes in a limited number of participants. Our findings should be confirmed in prospective studies with a larger number of participants.

Acknowledgement

This study was supported by a Grant for Scientific Research from

the Ministry of Education, Science, Sports and Culture (awarded to M. Sumitani). The authors acknowledge Drs. Tonosu J, Kato S, Ohya J, Oichi T, and Okamoto N for their valuable assistance.

References

- 1 Loeser JD, Treede RD (2008) The Kyoto protocol of IASP Basic Pain Terminology. *Pain* 137: 473-477.
- 2 Wilkie DJ, Huang HY, Reilly N, Cain KC (2001) Nociceptive and neuropathic pain in patients with lung cancer: a comparison of pain quality descriptors. *J Pain Symptom Manage* 22: 899-910.
- 3 Sumitani M, Miyauchi S, McCabe CS, Shibata M, Maeda L, et al. (2008) Mirror visual feedback alleviates deafferentation pain, depending on qualitative aspects of the pain: a preliminary report. *Rheumatology (Oxford)* 47: 1038-1043.
- 4 Bennett MI, Attal N, Backonja MM, Baron R, Bouhassira D, et al. (2007) Using screening tools to identify neuropathic pain. *Pain* 127: 199-203.
- 5 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.
- 6 Freynhagen R, Tölle TR, Gockel U, Baron R (2016) The painDETECT project - far more than a screening tool on neuropathic pain. *Curr Med Res Opin* 32: 1033-1057.
- 7 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: e68013.
- 8 Baron R, Jansen JP, Binder A, Pombo-Suarez M, Kennes L, et al. (2016) Tolerability, Safety, and Quality of Life with Tapentadol Prolonged Release (PR) Compared with Oxycodone/Naloxone PR in Patients with Severe Chronic Low Back Pain with a Neuropathic Component: A Randomized, Controlled, Open-label, Phase 3b/4 Trial. *Pain Pract* 16: 600-619.
- 9 Baron R, Kern U, Müller M, Dubois C, Falke D, et al. (2015) Effectiveness and Tolerability of a Moderate Dose of Tapentadol Prolonged Release for Managing Severe, Chronic Low Back Pain with a Neuropathic Component: An Open-label Continuation Arm of a Randomized Phase 3b Study. *Pain Pract* 15: 471-486.
- 10 Baron R., Likar R., Martin-Mola E., Blanco F.J., Kennes L., et al. (2016) Effectiveness of Tapentadol Prolonged Release (PR) Compared with Oxycodone/Naloxone PR for the Management of Severe Chronic Low Back Pain with a Neuropathic Component: A Randomized, Controlled, Open-Label, Phase 3b/4 Study. *Pain Pract* 16: 580-599.
- 11 Baron R, Martin-Mola E, Müller M, Dubois C, Falke D, et al. (2015) Effectiveness and Safety of Tapentadol Prolonged Release (PR) Versus a Combination of Tapentadol PR and Pregabalin for the Management of Severe, Chronic Low Back Pain With a Neuropathic Component: A Randomized, Double-blind, Phase 3b Study. *Pain Pract* 15: 455-470.
- 12 Schukro RP, Oehmke MJ, Geroldinger A, Heinze G, Kress HG, et al. (2016) Efficacy of Duloxetine in Chronic Low Back Pain with a Neuropathic Component: A Randomized, Double-blind, Placebo-controlled Crossover Trial. *Anesthesiology* 124: 150-158.
- 13 Mercadante S, Porzio G, Ferrera P, Aielli F, Adile C, et al. (2012) Tapentadol in cancer pain management: a prospective open-label study. *Curr Med Res Opin* 28: 1775-1779.
- 14 Cappelleri JC, Bienen EJ, Koduru V, Sadosky A (2014) Measurement properties of painDETECT by average pain severity. *Clinicoecon Outcomes Res* 6: 497-504.
- 15 Höper J, Helfert S, Heskamp ML, Maihöfner CG, Baron R (2014) High concentration capsaicin for treatment of peripheral neuropathic pain: effect on somatosensory symptoms and identification of treatment responders. *Curr Med Res Opin* 30: 565-574.
- 16 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.
- 17 Melzack R (1987) The short-form McGill Pain Questionnaire. *Pain* 30: 191-197.
- 18 Ware JE, Sherbourne CD (1992) The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care* 30: 473-483.
- 19 McHorney CA, Ware JE, 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.
- 20 Bouhassira D, Attal N, Fermanian J, Alchaar H, Gautron M, et al. (2004) Development and validation of the Neuropathic Pain Symptom Inventory. *Pain* 108: 248-257.
- 21 Yamaguchi M, Kumano H, Yamauchi Y, Kadota Y, Iseki M. (2007) The Development of a Japanese Version of the Short-Form McGill Pain Questionnaire. *JJSPC* 14: 9-14.
- 22 Matsubayashi Y, Takeshita K, Sumitani M, Oshima Y, Tonosu J, et al. (2015) Psychometric Validation of the Japanese Version of the Neuropathic Pain Symptom Inventory. *PLoS One* 10: e0143350.
- 23 Fukuhara S, Ware JE, Kosinski M, Wada S, Gandek B (1998) Psychometric and clinical tests of validity of the Japanese SF-36 Health Survey. *J Clin Epidemiol* 51: 1045-1053.
- 24 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: discussion 87.
- 25 Dimopoulou C, Athanasoulia AP, Hanisch E, Held S, Sprenger T, et al. (2014) Clinical characteristics of pain in patients with pituitary adenomas. *Eur J Endocrinol* 171: 581-591
- 26 Valdes AM, Suokas AK, Doherty SA, Jenkins W, Doherty M (2014) History of knee surgery is associated with higher prevalence of neuropathic pain-like symptoms in patients with severe osteoarthritis of the knee. *Semin Arthritis Rheum* 43: 588-592.
- 27 Hiyama A, Watanabe M, Katoh H, Sato M, Sakai D, et al. (2015) Evaluation of quality of life and neuropathic pain in patients with low back pain using the Japanese Orthopedic Association Back Pain Evaluation Questionnaire. *Eur Spine J* 24: 503-512.