The Application of Neuropathic Pain Questionnaires in Burning Mouth Syndrome Patients

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Aims: To evaluate and compare the validity of the PainDETECT, DN4, and abbreviated DN4 (DN4i) neuropathic pain questionnaires for primary burning mouth syndrome (BMS), which is a burning sensation in the oral mucosa in the absence of any identifiable organic etiology. **Methods:** Eighty-one patients (42 with primary BMS and 39 with nociceptive pain) complaining of a burning sensation and pain in their oral mucosa were enrolled in this study. All of the patients completed the neuropathic pain questionnaires. The sensitivity, specificity, positive predictive value, negative predictive value, and the area under the receiver operating characteristic (ROC) curve were estimated. Then the relationship between pain intensity and total neuropathic pain score was investigated. Data were analyzed with the chi-square test and independent *t* test for subjects' baseline characteristic differences, and with Pearson correlation coefficients for the relationship of variables. **Results:** The mean area under the ROC curves (AUCs) for PainDETECT, DN4, and DN4i were 0.81, 0.79, and 0.81, respectively. There was no statistically significant difference in the AUCs among the questionnaires. PainDETECT, DN4, and DN4i had a lower sensitivity and specificity for BMS compared to previous validation studies. The total scores for PainDETECT, DN4, and DN4i in the primary BMS group were significantly associated with pain intensity. **Conclusion:** Although the results of this study suggest that neuropathic pain questionnaires, such as PainDETECT and DN4, are not ideal principal screening tools for BMS patients, a substantial proportion of neuropathic symptoms in primary BMS patients were identified. *J Oral Facial Pain Headache 2015;29:177–182. doi: 10.11607/ofph.1326*

Key words: *burning mouth syndrome, DN4, neuropathic pain questionnaire, PainDETECT*

Primary burning mouth syndrome (BMS) is a burning sensation in the oral mucosa in the absence of any identifiable organic etiology. The reported prevalence of BMS varies from 0.7% to 15% because of vague diagnostic criteria.[1–4] BMS usually occurs in middle-aged and elderly women.[5] The most affected site is the tongue, particularly the tip and anterior two-thirds, but BMS can also involve the lips, palate, and gingiva.[6,7] Although there are several etiologic factors, including local, systemic, and psychologic factors, the exact mechanisms underlying BMS have not been elucidated.[8] Neurophysiologic, psychophysical, neuropathologic, and functional imaging studies have provided evidence that primary (idiopathic) BMS may be a chronic neuropathic pain disorder with peripheral and central mechanisms.[7–17] When factors are found that are related to dry mouth, oral infection, autoimmune mucosal disease such as oral lichen planus, allergy, nutritional deficiency, certain medication, or endocrine disorders (diabetes and thyroid disease), the patient is diagnosed with secondary BMS, for which the treatment aims to eliminate such etiologic factors.

Several neuropathic pain questionnaires have been introduced and validated as screening tools for neuropathic pain.[18] They are easy to use, do not require special equipment or clinical examinations, and are inexpensive. Most neuropathic pain questionnaires have a high sensitivity and specificity. Thus, neuropathic pain questionnaires are highly efficient and cost-effective for diagnosing neuropathic pain. Recently, the PainDETECT[19] and DN4[20] (Douleur Neuropathique 4 questions) questionnaires have been developed as screening tools for neuropathic pain.

The PainDETECT questionnaire was originally developed and validated in Germany for identifying neuropathic pain in patients with chronic lower-back pain. This questionnaire has a high sensitivity and specificity, and a good positive predictive accuracy (85%, 80%, and 83%, respectively). The DN4 questionnaire was developed and validated in France. The DN4 also has excellent sensitivity and specificity (82.9% and 89.9%, respectively) for neuropathic pain. The DN4 questionnaire also can be used as seven sensory items for evaluating neuropathic pain (called the DN4 interview, or DN4i) and has similar results.

Diagnosing primary BMS is mainly based on clinical features and is established after all other possible causes have been excluded.[21] There is no specific examination for BMS; thus, diagnosing BMS is difficult and challenging.[22] Considering that primary BMS has a possible neuropathic component, the purpose of the present study was to evaluate and compare the validity of the PainDETECT, DN4, and DN4i neuropathic pain questionnaires for primary BMS.

Materials and Methods

The study was approved by the Institutional Review Board of Pusan National University Dental Hospital (PNUDH-2013-026). Each patient provided informed consent to participate in this study.

Development of the Korean Versions of the PainDETECT and DN4 Questionnaires

Two native Korean translators fluent in English independently translated the PainDETECT and DN4 questionnaires. Two orofacial pain specialists edited the translations. Thereafter, one native English speaker who was fluent in Korean performed back translations of the translated PainDETECT and DN4 questionnaires. Comparing the original versions of the PainDETECT and DN4 questionnaires with reverse-translated versions, the Korean versions were modified and completed by the authors.

Subjects

Eighty-one consecutive patients complaining of burning sensation and pain in their oral mucosa and who visited the Department of Oral Medicine, Pusan National University Dental Hospital, were included in this study. Among them, 42 patients were placed in the primary BMS group, and 39 patients were placed in the nociceptive pain group, which consisted of patients with apparent oral lichen planus, hyposalivation, oral candidiasis, oral ulcer, or other oral viral infection (recurrent herpetic stomatitis).

The inclusion criteria for the primary BMS group were as follows:

- Experiencing a burning sensation in the mouth for more than 4 months
- Absence of detectable oral mucosal changes based on a careful oral examination
- Normal salivary flow rate (unstimulated whole saliva > 0.1 mL/min, collected for 5 min by spitting method; and stimulated whole saliva > 0.7 mL/min, collected for 5 min by chewing gum base and spitting)
- Oral swab culture and negative findings for candidiasis
- Normal blood test (complete blood count, blood glucose, and serum iron, ferritin, vitamin B12, folic acid, zinc, thyroid hormones T3 and T4, and thyroid-stimulating hormone)
- No history of a systemic condition possibly associated with an oral burning sensation (eg, uncontrolled diabetes, hypertension, thyroid disease, and autoimmune disease)

The exclusion criteria were as follows:

- Use of certain medications[22] associated with oral burning pain (eg, angiotensin-converting enzyme [ACE] inhibitors, diuretics, and antidepressants)
- Patients treated and being treating with psychologic therapies (including antidepressants such as selective serotonin reuptake inhibitors [SSRIs], and anticonvulsants)
- History of an allergy to dental materials (if patients had a lichenoid reaction, a patch test was carried out)
- Inability to complete the neuropathic pain questionnaires

Data Collection

At the first visit, all of the patients were asked to complete the neuropathic pain questionnaires. For physical examinations of DN4, testing dynamic mechanical allodynia (item 10) was carried out by applying a soft brush on the painful area three times, including the area of ulceration if present, while testing static mechanical allodynia (item 8) was carried out by a tactile test using a light finger contact on the painful area. The testing of item 9 was carried out using a dull-pointed periodontal probe. Also, item 5 in PainDETECT was slightly modified and applied to patients as: "Is cold or hot water drinking accompanied by some pain or discomfort in your mouth?"

Demographic data (age, sex, and duration and location of symptoms) and medical history (including current medications) were also investigated. Pain intensity was calculated using an 11-point numeric rating scale (NRS), where 0 was defined as no pain and 10 as the worst pain imaginable. The PainDETECT consists of 9 items, including 7 weighted sensory

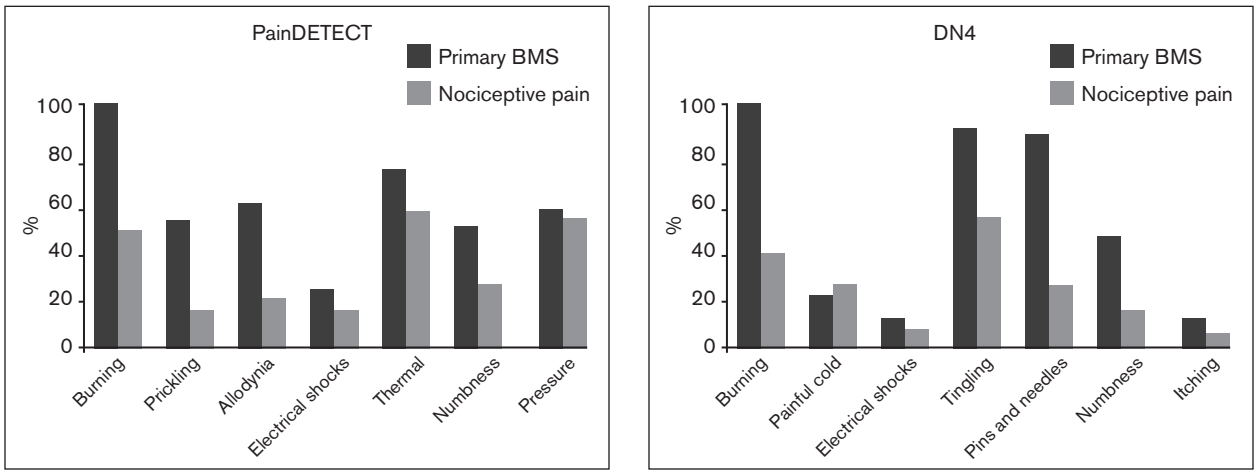

Fig 1 Sensory descriptive items of PainDETECT and DN4 in the primary BMS and nociceptive pain groups.

descriptive items (never to very strongly; 0 to 5 points), 1 item for pain radiating pattern (0 or 2 points), and 1 item for pain temporal pattern (–1 to 1 point). Its total scores range from –1 to 38; a total score ≥ 19 indicates that neuropathic pain is likely and a total score ≤ 12 that neuropathic pain is unlikely, whereas a score ≥ 13 but ≤ 18 is ambiguous or possible neuropathic pain. The DN4 questionnaire consists of 10 items. Its total score ranges from 0 to 10; a total score ≥ 4 indicates that neuropathic pain is likely. The DN4i score was separately calculated; a score of 3 points validates the diagnosis of neuropathic pain.

Statistical Analyses

The categorical variables were summarized as counts and percentages, and the numeric variables as the mean ± standard deviation (SD). Differences in patients' baseline characteristics were compared across the subgroups by using the chi-square test for categorical variables and independent *t* test for numeric variables, and the relationship of variables was analyzed with Pearson correlation coefficients. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and the area under the receiver operating characteristic (ROC) curve were estimated. The cutoff value was the value that maximized the sum of sensitivity and specificity values, which was calculated by the statistical program used. All of the statistical analyses were performed using SPSS version 21.0 software. *P* values less than .05 were considered to be statistically significant.

Results

Patient Demographics

The patients' age and sex distribution are indicated in Table 1. There was no significant difference in age and sex between the primary BMS and nociceptive pain groups. The nociceptive pain group comprised the following disease categories: oral lichen planus (15, 38.4%), hyposalivation (7, 17.9%), oral candidiasis (5, 12.8%), oral ulcer (5, 12.8%), and other oral viral infection (7, 17.9%). The PainDETECT and DN4 sensory descriptive items for all of the patients are presented in Fig 1.

Table 1 Demographic Data of Study Patients

	Primary BMS (n = 42)	Nociceptive pain (n = 39)	*P* value
Sex			
Female	35 (83.3%)	32 (82.1%)	.879
Male	7 (16.7%)	7 (17.9%)	
Age, mean ± SD (y)	62.30 ± 10.08	61.58 ± 12.06	.773

By chi-square test and independent *t* test.

Table 2 Area Under ROC curves of PainDETECT, DN4, DN4i

	Area under ROC curve (mean ± SE)	95% CI
PainDETECT	0.813 ± 0.052	0.714–0.891
DN4	0.795 ± 0.047	0.699–0.877
DN4i	0.811 ± 0.044	0.709–0.890

ROC = receiver operating characteristic; CI = confidence interval.

Validity

The area under the ROC curves (AUCs) for the PainDETECT, DN4, and DN4i questionnaires are presented in Table 2. There were no statistically significant differences in the mean AUCs among the questionnaires. The ROC curves for the PainDETECT, DN4, and DN4i questionnaires are shown in Fig 2. The optimal cutoff value for each questionnaire was 9, 4, and 3, respectively.

Table 3 Sensitivity, Specificity, Positive Predictive Value (PPV), and Negative Predictive Value (NPV) of Each Questionnaire

Questionnaire		Primary BMS (n = 42)	Nociceptive pain (n = 39)	Sensitivity	Specificity	PPV	NPV
PainDETECT	≥ 13	30	8	71.4%	79.5%	78.9%	72.1%
	< 13	12	31	(30/42)	(31/39)	(30/38)	(31/43)
	≥ 19	7	1	16.7%	97.4%	87.5%	52.1%
	< 19	35	38	(7/42)	(38/39)	(7/8)	(38/73)
DN4	≥ 4	25	7	59.5%	82.1%	78.1%	65.3%
	< 4	17	32	(25/42)	(32/39)	(25/32)	(32/49)
DN4i	≥ 3	29	10	69.1%	74.4%	74.4%	69.0%
	< 3	13	29	(29/42)	(29/39)	(29/39)	(29/42)

Values in parentheses reflect calculations as follows:
Sensitivity = Primary BMS (cutoff value≥)/All Primary BMS; Specificity = Nociceptive pain (cutoff value<)/All Nociceptive pain;
PPV = Primary BMS (cutoff value≥)/Primary BMS (cutoff value≥) + Nociceptive pain (cutoff value≥);
NPV = Nociceptive pain (cutoff value<)/Primary BMS (cutoff value<) + Nociceptive pain (cutoff value<).

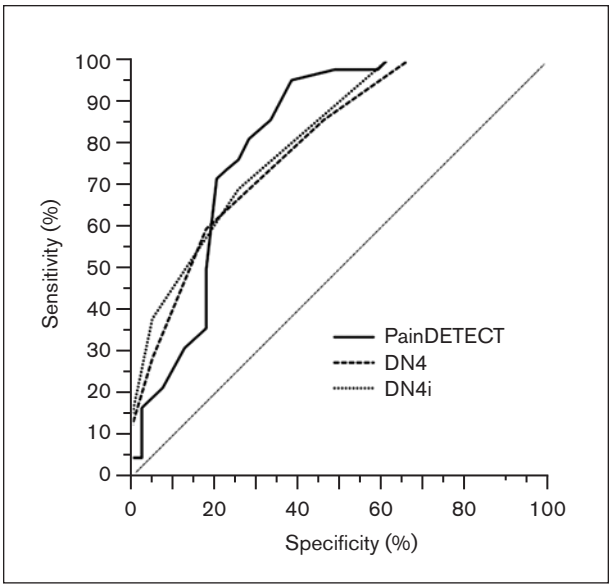

Fig 2 ROC curves of PainDETECT, DN4, and DN4i.

Table 4 Relationship Among Neuropathic Pain Scores and Pain Intensity and Symptom Duration

Questionnaire	Pain intensity	Symptom duration
PainDETECT	0.540*	0.211
DN4	0.359*	0.137
DN4i	0.398*	0.151

By Pearson correlation coefficients.
*$P < .001$.

In the primary BMS group, 7 patients (16.7%) had a total PainDETECT score ≥ 19, and 30 patients (71.4%) had a PainDETECT score ≥ 13. For the PainDETECT questionnaire, when 13 points was set as the cutoff value, its sensitivity, specificity, and PPV were found to be 71.4%, 79.5%, and 78.9%, respectively. For the DN4 questionnaires, 25 patients (59.5%) had a total score ≥ 4 and 29 patients (69.1%) had a DN4i score ≥ 3.

The sensitivity, specificity, PPV, and NPV for each questionnaire are presented in Table 3.

Relationship Among Neuropathic Pain Scores, Pain Intensity, and Disease Duration

In the primary BMS group, the mean scores ± SD for the PainDETECT, DN4, and DN4i questionnaires were 14.38 ± 4.98, 3.88 ± 1.27, and 3.23 ± 1.1, respectively. The mean duration and pain intensity in the primary BMS group were 14.76 ± 21.05 and 6.63 ± 1.72, respectively.

The total scores for the PainDETECT, DN4, and DN4i questionnaires in the primary BMS group were significantly associated with pain intensity ($P < .001$). However, the total score of each questionnaire was not significantly associated with pain duration ($P > .05$) (Table 4).

Discussion

Neuropathic pain results from causes that are different from those producing nociceptive pain, and it is discrete in its clinical symptoms, which are varied and complicated for a diagnostic evaluation. In addition to a conventional clinical examination, nerve conduction velocity and somatosensory-evoked potential recordings may be used, but they may have limited diagnostic value.[23,24] Additionally, quantitative sensory testing (QST) requires expensive equipment and long chair time, so its clinical use during the first visit is rather limited, although its specificity is undoubtedly high.[23] QST for BMS patients may be unnecessary because this testing is time-consuming, expensive, and its sensitivity and specificity are not validated. Accordingly, the clinical demand for a simple questionnaire-type examination has resulted in the creation of various neuropathic pain-related questionnaires. Such questionnaires have a high sensitivity and specificity, do not require any complicated instrumentation or clinical examination,

and are more acceptable to patients. Given such advantages, these questionnaires also have been used to evaluate fibromyalgia,[25] osteoarthritis,[26,27] and other musculoskeletal diseases.[28] Therefore, to test their clinical applicability for BMS patients, the two most widely used neuropathic pain questionnaires were evaluated in this study. Currently, there are no published studies using neuropathic pain questionnaires for BMS patients and age- and sex-matched controls.

The AUC represents the accuracy and reliability of the test; the diagnostic value is very high if an AUC is greater than 0.9, is of moderate value for AUCs between 0.7 and 0.9, and is of little clinical applicability for AUCs between 0.5 and 0.7 and of no value of AUCs less than 0.5.[29] The AUC values for the PainDETECT, DN4, and DN4i questionnaires were 0.81, 0.79, and 0.81, respectively, compared to respective AUCs of 0.92, 0.91, and 0.87 in previous studies.[19,20]

The ROC curve also represents the balance between sensitivity and specificity. In the present study, the PainDETECT questionnaire had an optimal cutoff value of 9 points with a sensitivity of 95.2% and a low specificity of 61.5%. Meanwhile, as in the original validation study, the DN4 questionnaire had an optimal cutoff value of 4, but its sensitivity was low at 59.5% and its specificity was high at 82.1%. The DN4i questionnaire revealed an equivalent optimal cutoff value of 3, while its sensitivity and specificity were low compared with the original validation study. For the PainDETECT questionnaire, although a score greater than 19 points confirms the diagnosis of neuropathic pain, when 13 points was set as the cutoff value, its sensitivity, specificity, and PPV were found to be 71.4%, 79.5%, and 78.9%, respectively.

The results of this study suggest that the neuropathic pain questionnaires are not qualified to be key screening tools for diagnosing primary BMS. Although there is one report on the DN4 questionnaire in dental treatment–related secondary BMS,[30] current studies on primary BMS are uncommon. Another preliminary study[31] using the DN4 questionnaire for primary BMS reported that 13 out of 22 patients (59%) scored greater than 4 points (cutoff value), and 14 patients (64%) above a cutoff value of 3 points for the DN4i questionnaire had a sensitivity of 78% and specificity of 81%. Thus, the authors concluded that the DN4 and DN4i questionnaires are effective screening tools for diagnosing primary BMS and confirmed the neuropathic nature of primary BMS. However, the results of the present study are not consistent with the above study, showing a relatively low sensitivity and specificity, although a cutoff value similar to previous studies was used.

Whereas no study has used the PainDETECT questionnaire for BMS patients, Ukwas and coworkers[32] reported the ineffectiveness of the PainDETECT questionnaire in patients with orofacial pain, and Elias and coworkers[33] found the inappropriateness of the present format of the PainDETECT questionnaire for trigeminal nerve–damaged patients. The present study supports these findings in that the PainDETECT questionnaire was not a reliable screening tool for diagnosing primary BMS because the questionnaires had a low sensitivity of 16.7% but a specificity of 97.4% (using a cutoff value of 19 points).

The present findings may be explained first by the ambiguity of the cause of BMS. BMS cannot be categorized into a single pain type of either nociceptive pain or neuropathic pain; rather, these two types of pains in BMS patients are associated with other psychologic and local factors, which is consistent with previous studies on the use of a questionnaire-type examination for fibromyalgia, another mixed-pain type disease.[34] The validation and reliability study for the neuropathic pain questionnaires likely excluded such mixed-pain diseases. Second, the applicability of the PainDETECT questions was actually limited in the description of orofacial pain; for example, the question "Is light touching (clothing, a blanket) in this area painful?" cannot appropriately describe orofacial pain. In place of such questions, a more orofacial pain–based question such as "Is soft food or light touch of the tongue inside the mouth painful?" should be adopted for orofacial pain conditions.[33] Third, screening tools fail to identify approximately 10% to 20% of clinically diagnosed neuropathic pain patients; accordingly, questionnaires alone cannot replace clinical judgment.[18]

In the present study, the total score for each questionnaire and pain intensity showed a statistically significant correlation, while no statistically significant correlation was found between the total score and pain duration, both of which support previous studies.[19,27,33] Considering the relationship between the neuropathic pain score and pain intensity, the application of neuropathic pain questionnaires has potential to be an effective evaluation method for neuropathic treatment effects.[35]

Limitations of the present study included a small sample size and that the education level of the patients was not considered. Additionally, the reliability of the PainDETECT and DN4 questionnaires for BMS has not been fully evaluated. Moreover, in the process of translating the original questionnaires into Korean, a possible cultural and language bias also could have developed. However, the study is the first that is based on BMS patient groups with age- and sex-matched controls in which different neuropathic pain questionnaires were used. Future studies with a large sample size and modified neuropathic questionnaire are warranted to develop a more effective screening tool for diagnosing primary BMS.

Conclusions

The results of the present study suggest that neuropathic pain questionnaires such as PainDETECT and DN4 may have lower sensitivity and specificity for the diagnosis of primary BMS than for other neuropathic pains. However, using these neuropathic pain questionnaires, the study identified a substantial proportion of neuropathic pain components in BMS patients. Therefore, neuropathic pain questionnaires may be an ancillary measurement tool for diagnosing and treating primary BMS patients.

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The authors report no conflict of interest related to this study.

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