

# Impact of Criteria-Based Diagnosis of Burning Mouth Syndrome on Treatment Outcome

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***Aims:** Burning mouth syndrome (BMS) primarily affects postmenopausal women and is often difficult to treat successfully. Treatment outcomes have been problematic because of failure to distinguish between patients with BMS and patients presenting with oral burning (OB) resulting from other clinical abnormalities. The purpose of this study was to determine characteristics that might uniquely identify BMS patients from patients with OB and to determine whether proper classification influences treatment outcome. **Methods:** The clinical sample consisted of 69 patients (83% female) with an average age of 62 years, pain duration of 2.45 years, and visual analog scale pain rating of 49 mm (rated from 0 to 100 mm). All patients underwent a clinical exam and completed the Multidimensional Pain Inventory and Symptom Checklist 90-Revised. **Results:** There were no differences between the BMS and OB groups with respect to age, pain duration, pain intensity, life interference, and levels of psychologic distress. Patients with OB demonstrated more clinical abnormalities than BMS patients. Hyposalivation and greater use of prescription medications, most notably hormone replacement therapy, were more common in the OB group compared with the BMS group. When treatment was provided that corrected an identifiable abnormality, significantly more OB than BMS patients reported greater than 50% relief from baseline pain rating. **Conclusion:** These data indicate that while BMS and OB groups may initially present with similar clinical and psychosocial features, they are distinguishable with careful diagnosis that often enables successful management of symptoms for each group.*

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**Key words:** burning mouth syndrome, classification, treatment outcome, psychological distress

**B**urning mouth syndrome (BMS) is a condition characterized by unexplained complaints of burning pain in the oral mucosa, particularly the tongue, that are present throughout the day and tend to worsen progressively by evening and during times of stress.<sup>1</sup> It is distinct from the symptom of oral burning (OB) sensation that results from any of a number of drugs or disorders. The estimated prevalence of BMS is 1% to 5% of the adult population.<sup>2,3</sup> The disorder has been reported to affect primarily postmenopausal women, with a 3- to 6-fold higher prevalence for women than men.<sup>2,4-6</sup> The mean age of BMS patients is between 55 and 60 years, with occurrence of the condition in persons under age 30 being rare.<sup>2,7</sup>

Unfortunately, the etiology and pathogenesis of BMS remain unknown, making it difficult for physicians and dentists to treat

this condition successfully. The management of patients has been attempted by addressing specific possible causal factors. Such factors that have been studied include: candidiasis<sup>5,8</sup>; vitamin/mineral deficiencies (B<sub>12</sub>, iron, folate, B<sub>1</sub>, B<sub>2</sub>, B<sub>6</sub>)<sup>5,9</sup>; diabetes mellitus<sup>5,9,10</sup>; environmental factors (ie, esophageal reflux, oral parafunctional habits)<sup>9</sup>; geographic tongue<sup>11</sup>; xerostomia<sup>5,9,11</sup>; and salivary disturbances.<sup>12</sup>

Treatment outcomes have been problematic because of failure to distinguish between patients with BMS and patients presenting with OB sensation resulting from clinical abnormalities or adverse effects of drugs. It is our view that a careful diagnostic evaluation to rule out identifiable clinical abnormalities and medications that may cause OB is key to the successful management of this group of individuals. The purpose of this study was to determine characteristics that might uniquely identify patients with BMS from patients with OB and to determine whether proper classification influences treatment outcome.

## Methods

### Sample

Consecutive patients who reported symptoms of OB were recruited from the Orofacial Pain Center at the University of Kentucky during the years 1990 to 1999. The clinical sample consisted of 69 participants (83% women, 100% Caucasian) with an average age of 62.43 years (range 27 to 88 years; standard deviation (SD) = 12.79) and mean pain duration of 2.45 years (range 0.10 to 20 years; SD = 3.52). Inclusion criteria for study participation included: (1) symptoms of diffuse, burning pain of the tongue and/or oral mucosa; (2) OB pain rated greater than 10 mm on a 100-mm visual analog scale (VAS), where 0 represented "no pain" and 100 represented "worst possible pain"; and (3) selection of the descriptor "burning" from the McGill Pain Questionnaire (MPQ)<sup>13</sup> with an intensity that equaled or exceeded all other pain descriptors. The criterion for exclusion was inability to communicate or to complete written forms. Study participants were asked at the time of initial evaluation whether or not they would like to participate in the research study. One patient who declined participation was excluded. The study was approved by the University of Kentucky Institutional Review Board for the Protection of Human Subjects.

## Psychometric Instruments

Study participants completed the MPQ,<sup>13</sup> the Multidimensional Pain Inventory (MPI),<sup>14</sup> and the Symptom Checklist-90-Revised (SCL-90-R)<sup>15</sup> during the initial clinical evaluation. The MPQ is a 15-item scale that includes a sensory pain rating scale composed of 11 verbal descriptors and an affective pain rating scale that includes 4 verbal descriptors. The 11 items on the sensory scale were each rated from 0 to 3 (0 = none and 3 = severe sensory quality) and summed for the sensory pain score. Each item on the 4-item affective scale was rated on the same 0 to 3 scale and items were summed for the affective pain score. The MPQ also has a 100-mm VAS for rating overall pain severity from 0 to 100, where "0" represents "no pain" and "100" represents "worst possible pain." The MPI is a comprehensive, self-report instrument comprising 61 items that yield psychosocial (ie, pain severity, life interference, life control, affective distress) and behavioral indices of the influence of the current pain experience. Test-retest reliabilities of individual scale scores range from  $r = 0.68$  to  $0.86$ , and coefficient alphas or internal consistencies range from  $r = 0.73$  to  $0.90$ .<sup>14</sup> The SCL-90-R is a 90-item self-report measure that provides a general assessment of psychiatric symptoms, with 9 scales reflecting a broad range of psychopathology. The scales include somatization, obsessive-compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, psychoticism, and an overall general symptom index (Global Severity Index). Test-retest reliabilities of individual SCL-90-R scale scores with non-psychiatric patient samples range from  $r = 0.78$  to  $0.90$ , and coefficient alphas or internal consistencies range from  $r = 0.77$  to  $0.90$ .<sup>15</sup>

## Procedure

All participants were evaluated by a dentist with advanced training in oral medicine who conducted the clinical exam and recorded historical information. Following completion of a comprehensive oral examination, participants were informed of the purpose of the research and, if willing, completed a consent form. All participants provided venous blood for hematologic evaluation (ie, complete blood count with differential and fasting blood glucose). Whole, expectorated saliva was collected for 5 minutes for determination of flow rate and fungal cultures. Saliva was cultured on Saboraud's agar for the presence of fungal organ-

**Table 1** Criteria for Distinguishing Oral Burning (OB) Group from Burning Mouth Syndrome (BMS) Group

	OB group	BMS group
Clinical examination	Mucosal atrophy, erosion, ulceration (eg, geographic tongue, oral candidiasis, lichen planus) at the site of oral burning, or parafunctional habit	Normal
Whole expectorated salivary flow rate	≤ 0.2 mL/min	> 0.2 mL/min
Laboratory		
CBC/differential	≤ 3.8 million red blood cells/mL for women or ≤ 4.2 million red blood cells/mL for men	> 3.8 million red blood cells/mL for women or > 4.2 million red blood cells/mL for men
Fasting glucose	> 124 mg/dL	≤ 124 mg/dL
Potential adverse drug effect	Taking a medicine documented to have an association with oral burning (eg, ACE inhibitors)	Not taking a medicine documented to have an association with oral burning

CBC = complete blood count; ACE = angiotension converting enzyme

isms. Participants were then given psychometric questionnaires (MPI, SCL-90-R) to complete and return to the investigators.

Psychometric data were scored and standardized through the use of a normal, non-clinical sample (n = 974) from the general population for the SCL-90-R<sup>15</sup> and from a general pain population presenting for treatment at a pain center (n = 300) for the MPI<sup>14</sup> prior to performing analyses. Standardized scores were expressed as T-scores where the mean is equal to 50 and SD is equal to 10. Transformation to T-scores enables the presentation of standardized scores without use of negative numbers. Standardization samples are widely accepted in the empirical literature and represent a reasonable means of comparing a sample of clinical data.

Based on results of the history and clinical, psychometric, salivary, and laboratory findings, study participants were assigned to either the OB group (ie, symptom of OB associated with an abnormality or drug identified during the diagnostic evaluation) or BMS group (ie, symptom of OB but no associated drug or abnormality identified during the diagnostic evaluation) according to the criteria listed in Table 1. Identification of 1 finding that could potentially cause the OB symptoms (eg, ulcerations, low salivary flow rate, low red blood cell count, high fasting glucose, use of medication associated with OB) was sufficient for inclusion in the OB group. Since this is the first study to identify specific criteria useful for distinguishing BMS

from OB, there are no sensitivity and specificity data available for these criteria.

The foundation of treatment for the OB group was based upon the alleviation of the clinical and laboratory abnormality identified. Treatment was provided on the basis of current standards.<sup>16</sup> Selection of medication was based on previous and current medications, medical contraindications, potential adverse effects, and the participant's desires. Subjects in the BMS group (ie, no identifiable clinical and laboratory abnormality) were prescribed norpramine (Desipramine, Geneva Pharmaceuticals) 10 mg before bed for 1 week, with escalation of 10 mg weekly up to 150 mg, or clonazepam (Klonopin, Roche Laboratories) 0.25 mg before bed for 1 week, with escalation of 0.25 mg weekly up to 3 mg based on previous and current medications, medical contraindications, potential adverse effects, and the participant's desires. Participants were instructed to increase the dose only until they experienced either significant pain relief or adverse effects. Adverse effects were annotated by the patient. Willing participants who gained less than 50% relief were provided combined therapy (norpramine + clonazepam), oxygen therapy, carbamazepine, or vitamins in a sequential manner. Clinical effects, adverse effects, and level of pain were recorded on the VAS at a 3-month structured telephone survey or clinical evaluation. Subjects were followed thereafter every 6 months, as willing.

Statistical analyses were conducted with the Statistical Package for the Social Sciences (SPSS) for Windows.<sup>17</sup> Differences between BMS and OB groups were tested with chi-square analyses for categorical variables and *t* tests for continuous variables. Family-wise errors for multiple comparisons of variables conceptually related to one another were controlled with the Bonferroni procedure.

## Results

### Psychologic Characteristics and Pain Ratings

Each of the participants' SCL-90-R raw scores was converted to standardized T-scores through the use of non-psychiatric patient adult norms. Average T-scores and SDs for the BMS and OB groups are presented in Table 2. With the Bonferroni corrections for family-wise error rate, there were no significant differences between the BMS and OB participants for any of the SCL-90-R individual subscale scores or for the overall level of psychologic distress (represented by the Global Severity Index). Further, average SCL-90-R T-scores for both groups suggest that psychologic distress was within an average range (not greater than 2 SDs above average), indicating that neither the BMS nor the OB participants reported symptoms suggestive of psychologic disturbance.

Average T-scores for the MPI scales were computed from a normative sample of pain patients. T-scores and SDs for MPI subscales for the BMS and OB groups are also reported in Table 2. Similar to SCL-90-R data, with the Bonferroni corrections there were no significant differences between groups for the life control, interference, pain severity, and affective distress subscales of the MPI. Also, there were no significant differences between participants endorsing a history of anxiety or depression symptoms (31% of BMS and 33% of OB subjects). In addition to pain ratings provided on the MPI, participants provided a VAS score of their current pain rating. Possible VAS scores ranged from 0 to 100 mm, with higher scores indicating greater pain severity. VAS pain ratings were 55.12 mm and 47.30 mm, with no significant differences between VAS ratings for the BMS and OB groups, respectively ( $P > .05$ ; see Table 2).

### Clinical Characteristics

Clinical characteristics of the BMS and OB groups are provided in Table 3. Significant differences were not noted between groups for pain duration

(in years); age; number of systemic illnesses; number of involved pain sites; number of teeth either decayed, missing, or filled; current smoking status; presence of an instigating event; perceived taste disturbance; perceived oral dryness; use of angiotensin-converting enzyme (ACE) inhibitors; anemia; geographical tongue; diabetes/abnormal glucose; or fungal infection ( $P > .05$ ). Participants with OB demonstrated more clinical abnormalities (46.55% of OB group versus 0% of BMS group,  $\chi^2 = 17.03$ ,  $P < .001$ ); hyposalivation (44.2% of OB group versus 0% of BMS group,  $\chi^2 = 16.22$ ,  $P < .001$ ); and greater use of prescription medications (mean = 4.35 prescriptions, SD = 3.58 for OB group; mean = 2.19 prescriptions, SD = 3.16 for BMS group;  $t$  test =  $-2.50$ ,  $P < .05$ ). Most notably, hormone replacement therapy was more common in the OB group compared with the BMS group (39.5% of OB group versus 11.5% of BMS group,  $\chi^2 = 6.17$ ,  $P < .05$ ).

### Clinical Outcomes

All subjects were followed for a minimum of 6 months. For the OB group, the mean follow-up period was 11.2 months (range 6 to 47 months). In the BMS group, the mean follow-up period was 10.5 months (range 6 to 48 months). When treatment was provided that corrected an identifiable abnormality, significantly ( $P < .05$ ) more OB than BMS participants reported greater than 50% relief from symptoms (72.5% versus 41.2%, respectively). Table 4 summarizes the specific clinical abnormalities and treatment responses of the OB group. The majority of BMS participants who were treated with nortriptyline and/or clonazepam, as described above, reported a significant decrease in symptoms (Table 5). Complete relief was gained with 3 agents (ie, nortriptyline, oxygen, and carbamazepine). The response to nortriptyline occurred generally at a low dose (less than 30 mg) and was seldom found to provide a benefit at doses greater than 50 mg. Oxygen was provided in an office setting at 100% and 4 to 5 L/minute. The beneficial effect of clonazepam was similar to previous findings,<sup>18</sup> with no patient reporting complete relief.

## Discussion

The purpose of this study was to determine clinical characteristics that would uniquely distinguish study participants with BMS from participants with OB, and, further, to determine whether

**Table 2** Psychologic Characteristics and Pain Ratings of BMS and OB Groups

	BMS group (n = 26)		OB group (n = 43)		t test
	Mean	SD	Mean	SD	
Psychologic variables					
Somatization	56.70	(9.82)	56.46	(10.82)	0.08
Obsessive-compulsive	55.74	(10.14)	57.56	(10.25)	-0.68
Interpersonal sensitivity	56.00	(10.79)	54.46	(9.79)	0.58
Depression	59.26	(8.52)	57.15	(9.07)	0.90
Anxiety	54.70	(11.34)	55.41	(9.73)	-0.26
Hostility	50.65	(9.25)	51.97	(11.02)	-0.48
Phobia	52.00	(9.56)	48.69	(6.74)	1.60
Paranoia	50.26	(9.59)	50.67	(9.84)	-0.16
Psychoticism	55.27	(9.07)	56.97	(10.87)	-0.62
Global severity	57.48	(10.13)	57.31	(9.55)	0.07
MPI affective distress	42.84	(11.13)	44.21	(11.44)	-0.46
Lifetime history of anxiety/depression	31%		33%		.02*
Pain-related variables					
MPI pain severity	41.99	(13.98)	38.63	(12.12)	0.98
MPI life control	52.99	(8.62)	51.90	(8.34)	0.49
MPI interference	30.60	(16.27)	25.96	(14.12)	1.17
VAS pain rating (0-100)	55.12	(17.82)	47.30	(23.61)	1.27

Note: No significant group differences were found for psychologic or pain characteristics.  
\* $\chi^2$  test.

**Table 3** Clinical Characteristics of BMS and OB Groups

	BMS group (n = 26)		OB group (n = 43)		Difference
	Mean	SD	Mean	SD	
Historical findings					
Pain duration (y)	2.27	(3.81)	2.56	(3.38)	-0.32 (t)
Age (y)	59.08	(12.40)	64.47	(12.73)	-1.72 (t)
<b>No. of prescription medications</b>	<b>2.19</b>	<b>(3.16)</b>	<b>4.35</b>	<b>(3.58)</b>	<b>-2.50* (t)</b>
No. of systemic illnesses	2.19	(1.65)	2.88	(1.85)	-1.56 (t)
No. of sites involved	1.96	(0.82)	1.95	(0.97)	0.04 (t)
Current smoker	11.5%		11.6%		0.00 ( $\chi^2$ )
Reported alcohol use	19.2%		14.0%		0.34 ( $\chi^2$ )
<b>Use of hormone replacement therapy</b>	<b>11.5%</b>		<b>39.5%</b>		<b>6.17* (<math>\chi^2</math>)</b>
Instigating event	61.5%		48.8%		1.05 ( $\chi^2$ )
Perceived taste disturbance	46.2%		46.5%		0.001 ( $\chi^2$ )
Perceived oral dryness	65.4%		62.8%		0.05 ( $\chi^2$ )
Use of Vasotec <sup>†</sup>	0%		2.3%		0.61 ( $\chi^2$ )
Clinical and lab findings					
No. of teeth decayed, missing, filled	19.96	(8.29)	22.74	(7.53)	-1.39 (t)
<b>Clinical abnormality</b>	<b>0%</b>		<b>46.5%</b>		<b>17.03*** (<math>\chi^2</math>)</b>
<b>Hyposalivation</b>	<b>0%</b>		<b>44.2%</b>		<b>16.22*** (<math>\chi^2</math>)</b>
Anemia	12%		23.3%		2.96 ( $\chi^2$ )
Geographical tongue	15.4%		11.6%		0.20 ( $\chi^2$ )
Diabetes/abnormal glucose	4%		16.3%		3.95 ( $\chi^2$ )
Positive fungal culture	3.8%		18.6%		3.17 ( $\chi^2$ )

\* $P < .05$ ; \*\* $P < .01$ ; \*\*\* $P < .001$ ; t test used for continuous variables,  $\chi^2$  test for categorical variables.

<sup>†</sup>An angiotensin-converting enzyme inhibitor drug given to patients with hypertension.

**Table 4** Clinical Characteristics and Treatment Outcomes of OB Group (n = 43)\*

Abnormality identified	n <sup>x</sup>	Treatment	Response categories <sup>†</sup>					
			a	b	c	d	e	f
Clinical examination								
Geographic tongue	3 <sup>2</sup>	Steroids	0	2	1	0	0	2
Fungal involvement								
Colonization	5 <sup>1</sup>	Antifungal medication	0	1	0	4	0	1
Oral infection	1		1	0	0	0	0	0
Systemic infection	0 <sup>1</sup>		0	0	0	0	0	1
Lichen planus	2	Topical steroids	0	2	0	0	0	0
Denture impingement	2 <sup>1</sup>	Denture readjustment and/or relining	2	0	0	0	0	1
Parafunctional habit	2	Awareness, counseling to discontinue habit, and/or biteguard	0	1	0	0	1	0
Whole expectorated salivary flow rate								
hyposalivation (≤ 0.2 mL/min)	17 <sup>4</sup>	Sialogogues	8	5	0	2	2	4
Laboratory blood studies CBC differential:								
Anemia (≤ 3.8 million red blood cells/mL)	5 <sup>3</sup>	Vitamins	1	1	1	1	1	3
Fasting glucose: Diabetes/abnormal glucose (> 124 mg/dL)	1 <sup>2</sup>	Glucose control (anti-diabetic medication)	0	1	0	0	0	2
Serum electrolytes: Elevated serum calcium	2		0	0	0	0	2	0
Potential adverse drug effect: Taking a medicine documented to have an association with oral burning (ie, ACE inhibitors)	2	Discontinue drug	1	1	0	0	0	0

\*The total number of reported clinical abnormalities is greater than the number of individuals in the OB group since some participants reported and/or were treated for more than 1 clinical abnormality.

n<sup>x</sup> represents the number of participants whose specific clinical abnormality was addressed in treatment; the exponent refers to participants with particular abnormalities that were not addressed in treatment.

<sup>†</sup>Response categories were as follows: (a) Complete relief; (b) > 50% relief; (c) < 50% relief; (d) No relief; (e) Noncompliant or did not accept recommended treatment; and (f) Abnormality not addressed in treatment.

CBC = complete blood count; ACE = angiotensin converting enzyme.

**Table 5** Treatment Outcomes of BMS Group (n = 26)

Treatment	Complete relief	> 50% relief	< 50% relief	No relief	Noncompliant
Norpramine	2	4	5	1	2
Norpramine and clonazepam	0	2	0	0	0
Norpramine and salagen	0	1	0	0	0
Clonazepam	0	1	1	0	0
Oxygen	1	0	0	0	0
Carbamazepine	1	0	0	0	0
Vitamins	0	1	0	0	0
Declined treatment	0	0	0	0	3
Spontaneous	1	0	0	0	0

proper classification was related to treatment outcome. Our data indicate that while BMS and OB groups may initially present with similar clinical and psychosocial features, they are distinguishable with careful diagnosis that often enables successful management of symptoms. Specifically, participants with symptoms of OB reported relief of symptoms (50% or greater relief for 72.5% of OB group) when treated for specific clinical abnormalities, such as steroids for geographical tongue,

antifungal medications for fungal infections, sialogogues for low salivary flow and xerostomia, vitamins for anemia, anti-diabetic medications for diabetes/abnormal glucose, and discontinuation of a particular medication associated with OB symptoms. For the BMS group, 13 of 26 patients reported greater than 50% relief of symptoms inclusive of all treatments. These results clearly indicate that differentiating participants with identifiable clinical abnormalities from those with BMS

generally results in effective treatments. The response of BMS participants was more variable than the OB group. Adding to the complexity of treatment is the fact that approximately 20% of these individuals are noncompliant or decline treatment, and a significant portion experience adverse effects that result in the choice to stop taking the medication.

Recent discussions concerning BMS have focused on the importance of careful diagnostic evaluation.<sup>19</sup> The present data support the value of distinguishing BMS as a clinical entity from OB, but diagnosis of BMS is currently one of exclusion. Accordingly, the findings from earlier studies may need to be interpreted carefully, given that it is often not clear whether participants with OB symptoms have been differentiated from BMS. The latter, with no well-understood pathophysiology at the present time, also contributes to difficulty in providing successful treatments.

The limited differences in psychologic symptomatology between patients with OB and BMS provide further evidence that these disorders, and BMS in particular, do not necessarily represent a psychologic disturbance, as has been suggested by earlier studies.<sup>20–22</sup> While it may be the case that individuals suffering from symptoms of OB, regardless of source, may have a difficult psychologic adjustment, we do not find evidence supporting the primary role of psychologic factors in the pathogenesis of OB disorders and BMS specifically. However, further study is needed to reconcile our findings with those of other clinical research facilities. It may be that our sample of patients is not representative of the type of patients seen in other clinics around the world.

Finally, the question of the etiology of BMS remains an enigma. The data from the OB group suggest that physiologic abnormalities precipitate and sustain symptoms of burning. When the abnormalities are corrected, these symptoms resolve. While the present data do not represent controlled clinical outcomes, they do suggest a consistent link between the described abnormalities and OB symptoms. Further research exploring the nature of the burning for a particular disorder may reveal clues concerning the underlying physiologic mechanisms that produce the burning sensations. These principles may then be used to explore the nature of burning for BMS patients. Recent evidence from our collaborative research studies suggests that altered concentrations of neuropeptide transmitters in BMS patients may be an important factor to explore in future research.

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