Self-Reported Symptoms Improvement and Dental Patient-Reported Outcome In Burning Mouth Syndrome Female Patients: A Pilot Study By Phone Interview

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Abstract

Primary burning mouth syndrome (BMS) is an idiopathic chronic pain disorder that can be characterized by a burning sensation of the oral cavity without the identifiable disease. Although pharmacological and non-pharmacological treatments have been used to manage primary BMS, a complete resolution of chronic pain symptoms in BMS is not common and the chronicity of pain can impair the patient's oral-health-related quality of life (OHRQoL). Due to the lack of patient-related outcomes in primary BMS studies, it is relevant to investigate whether primary BMS subjects are truly satisfied with the provided treatment and if the treatment has had any impact on their OHRQoL. This study aims to evaluate the sociodemographic data, clinical features and determine the patient global impression of change (PGI-C) and OHRQoL. Twenty patients with primary BMS were interviewed through telephone with 3 self-reported questionaries and specific data was retrieved from the subject's clinical charts. No significant differences in PGI-C and OHRQoL between different age groups, working status, treatment options, or psychological profile were found. Primary BMS patients reported large to small improvement and high OHRQoL status independent of the provided BMS treatments. The patient global improvement and OHRQoL were similar in BMS patients with a variety of follow-up durations.

Keywords**:** *burning mouth syndrome, chronic pain, symptoms improvement, self-reported, patient-reported outcome, oral-health related quality of life*

1. Introduction

Primary burning mouth syndrome (BMS) is a poorly understood, idiopathic chronic pain disorder that can be characterized by a burning sensation of the oral cavity in the absence of any identifiable organic disease (Komiyama et al., 2012). The prevalence of BMS reported for the general population varies between 0.7% and 15% and seems to depend on the diagnostic criteria used. BMS appears to be most prevalent in postmenopausal women, although younger women, as well as men, can also be affected. Moreover, BMS prevalence increases with age (Bender, 2018). Most of the studies were done in Europe (Farag et al., 2019). Mean age of primary BMS reported in Spain 64.9 years, Italy 67.3 years, Sweden 72.7 years, France 65 years, Argentina 57.5 years, Brazil 59.7 years, USA 63.8 years, Japan 61.3 years and China 60.5 years (Rodríguez de Rivera Campillo, López-López, & Chimenos-Küstner, 2010; Carbone et al., 2009; Silvestre et al., 2012; Gremeau-Richard et al., 2004; Lopez-D'alessandro & Escovich, 2011; Sugaya et al., 2016; Umezaki et al., 2016; Bessho et al., 1998; Yang et al., 2018). Since the etiology of primary BMS has remained largely unknown, current treatment options are quite diverse and lack a clear rationale for proper use.

Although there are several types of primary BMS treatment, the management for primary BMS is still a challenge due to high incompleted remission response and no standard treatment (Miziara et al., 2015). Primary BMS management can be divided into pharmacological and non-pharmacological options (Charleston, 2013). Both systemic and topical medications are widely used in primary BMS management. Systemic medication, for example, antidepressants (amitriptyline, paroxetine), anticonvulsants (gabapentin, pregabalin), benzodiazepines (clonazepam), antipsychotics (amisulpride), dietary supplements, and herbs (alpha-lipoic acid, cautuama) have been frequently used. Several topical agents have also been prescribed such as clonazepam, capsaicin, benzydamine, lactoperoxidase, and urea. For the patients who unresponsive to pharmacological treatment, there are also various non-pharmacological options, for instance, psychological

therapy (cognitive behavioral therapy), physical barrier (tongue protector), acupuncture, and low-level laser therapy (Feller et al., 2017; McMillan et al., 2016).

For a long time, pain clinicians were rating pain improvement in chronic pain conditions by using subjective scales/tools like visual analog scales or numeric rating or pain frequency scales. However, the limitations of these tools are biased by recall bias and they only measure pain in a specific moment in time (Gorral et al., 2016). To overcome these challenges and more objectively assess patient's satisfaction with chronic pain treatment, the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) has recommended the use of tools to measure the subject's ratings of overall improvement after treatment (Dworkin et al., 2005). Questionnaires like the patient global impression of change (PGI-C) were designed to be patient-centered and assess real patient satisfaction with the rendered treatment (Yue et al., 2020). The PGI-C has been adapted especially to assess how patients perceive a result from the treatments. This instrument is commonly used because of the simplicity and utilization (Perrot & Lanteri-Minet, 2018).

Orofacial pain is one of four domains that can impact the oral-health-related quality of life (OHRQoL). Assessing OHRQoL will allow clinicians to understand the impacts of a disease on a patient (John, 2018). Although orofacial pain disease like primary BMS is not a life-threatening disease but a complete resolution of pain symptoms in BMS is not common. Therefore, the chronicity of pain can impair patient OHRQoL. Chronic pain leads to disability days where patients do not want to work, do not want to socially interact, or perform normal daily routines including missing meals, leading to nutritional issues and oral flora imbalance, which can result in the cycle of chronic pain (Sulduker et al., 2019). So chronic pain management aims to break the ongoing cycle of chronic pain (Stone & Cole, 2014).

Patient-reported outcome measures such as the 5-item oral health impact profile (OHIP-5) are gaining increased attention to assess the OHRQoL after treatment of oral diseases without any clinician impression bias (John, 2018). Due to the lack of patient-related outcomes in primary BMS studies, it is relevant to investigate whether primary BMS subjects are truly satisfied with the prescribed treatment and if treatment has had any impact on their OHRQoL. Chronic pain related with emotional and physical function changes, thus it is important to assess other outcomes that associated with pain and treatment satisfaction in chronic pain study like BMS (Turk, 2003).

2. Objectives

1) To evaluate the sociodemographic data and clinical features of primary BMS patients treated at a dental specialty clinic

2) To determine PGI-C and OHRQoL (using OHIP-5 questionnaire) of primary BMS patients treated at a dental specialty clinic

3. Materials and Methods

3.1 Study design, participants, and instruments

This study was a retrospective survey performed in primary BMS patients who attended the Oral Medicine Clinic, Faculty of Dentistry, Chulalongkorn University from January 2015 to December 2020. All data collection was done through a comprehensive phone interview. The study protocol was approved by The Human Research Ethics Committee of the Faculty of Dentistry, Chulalongkorn University. Informed consent was requested prior to enrollment in this survey. A survey was conducted on the subjects that agreed to participate after inclusion criteria were met.

The inclusion criteria for this study included the subjects who (1) were previously diagnosed with primary BMS, (2) presented chronic pain in the oral mucosa for more than 3 months, and (3) had a minimum age of 18. The exclusion criteria were: (1) male, (2) unable to communicate with the Thai language by phone interview, (3) non-Asian, and (4) presence of poorly controlled mental illness(es).

Subjects who met the inclusion and exclusion criteria above were contacted by phone interview. All subjects were informed about the details of the study and were scheduled to give a phone interview with a maximum duration of 10 minutes. Phone interviews were separated into 2 sessions if they were unable to make the interview short or if there were disruptions due to poor phone signal/connection. During the phone

interview, the subject was given three questionnaires: PGI-C, OHIP-5, and Hospital anxiety and depression scale (HADS). The details of each questionnaire in the original version were shown in Figure 1-3.

Primary outcomes included data from the PGI-C and OHIP-5. The PGI-C is a 1-item questionnaire that requests an individual to rate the perceived change in the patient's condition in response to therapy at a specific endpoint (Mohebbi et al., 2018), which is a categorical scale that provides ratings from 1 to 7: 1 = very much better, 2 = much better, 3 = better, 4 = no change, 5 = worse, 6 = much worse, and 7 = very much worse (Hudson et al., 2009). A translated Thai version of PGI-C was used (Chinthakanun, 2019).

Regarding OHIP-5, this is a validated instrument with 5 items representing at least each of the four dimensions. This questionnaire was a 5-point ordinal scale (0 = never, 1 = hardly ever, 2 = occasionally, 3 = fairly often, and 4 = very often). All scores must be summed to calculate the final score ranging from 0 to 20. A larger score indicated more negative impacts of oral health problems (Simancas-Pallares et al., 2020). A translated Thai version of OHIP-5 was used as a part of the Thai version of OHIP-14 (Nammontri, 2017).

Hospital Anxiety–Depression Scale (HADS) is a 14-item self-assessment scale frequently used to evaluate psychological profiles and emotional stress in chronic pain patients. This instrument consists of 2 subscales, anxiety and depression, each subscale contains 7 items. For interpreting HADS, scores of greater than 10 were indicative of anxiety or depression case, scores of 7 or less were indicative of no significant anxiety and depression, and scores of 8 to 10 indicated borderline anxiety or depression (Braud & Boucher, 2016). A translated Thai version of HADS was used (Nilchaikovit, Lortrakul, & Phisansuthideth, 1996). All data related to sociodemographics (age, working status), follow-up duration, and provided BMS therapies were retrieved from the subject's clinical charts archived at the Oral Medicine Clinic.

3.2 Statistical analysis

The data were analyzed using the SPSS statistics program version 22.0 (SPSS Inc., Chicago, IL) at a significance level of 0.05. Descriptive statistics were used to determine the percentage and mean (95% confidence interval). An independent t-test was used to compare the outcome differences between age and follow-up duration. One-way ANOVA was used to compare the outcome differences between working and psychological status. No statistical analysis was performed on provided BMS therapy.

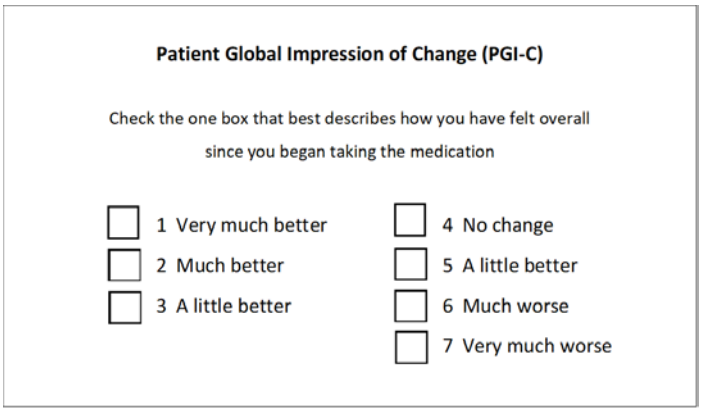

Figure 1 An original version of PGI-C

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:
Total score: Depression (D) _____ Anxiety (A) _____
0-7 = Normal
8-10 = Borderline abnormal (borderline case)
11-21 = Abnormal (case)

Figure 2 An original version of HADS

Oral Health Impact Profile-5 (OHIP-5)

How often have you had one or more of the following problem(s) during the last month?

	Very often	Fairly often	Occasionally	Hardly ever	Never
1. Have you had difficulty chewing any foods because of problems with your teeth, mouth, dentures or jaws?					
2. Have you had painful aching in your mouth?					
3. Have you felt uncomfortable about the appearance of your teeth, mouth, dentures or jaws?					
4. Have you felt that there has been less flavor in your teeth, mouth, dentures or jaws?					
5. Have you had difficulty doing your usual jobs because of problems with your teeth, mouth, dentures or jaws?					

Figure 3 An original version of OHIP-5

4. Results and Discussion

A total of 20 female subjects were enrolled in this study. Because the higher frequency of BMS in females over males was 5:1 (Feller et al., 2017), the authors excluded males from this study to eliminate hormonal confounding factors. The mean age of enrollment was 53.5 (46.8, 60.3) years, slightly lower than the number 59.4 of the study in Minnesota, which recruited 149 primary BMS subjects. According to WHO's definitions, patient's age was divided into 2 groups, young adult (18-65 years) and elderly (above 65 years) (WHO, 2001). The majority of our subjects were young adults with ages ranging from 26-72 years. Even though the sample size of this study was limited but the distribution was similar to the previous primary BMS study (Kohordt et al., 2016). The mean follow-up duration was 27.1 (16.9, 37.2) months. Over half of subjects (60%) had been follow-up for more than a year, but the authors observed no significant difference in symptoms improvement and OHRQoL.

PGI-C was used by IMMPACT recommendation as a tool for assessing the subject's rating of global improvement, one from 6 core outcomes to observed BMS RCTs (Turk et al., 2003). All subjects reported improvement in PGI-C with an average PGI-C score of 2.1 from a score range of 1-7. 60% of subjects report much better overall improvement while 25% and 15% reported little better and very much better improvement respectively. Our results showed much high improvement of the subject when compared with López-Jornet et al. who reported 40% of a little better and 47% of no change in improvement (López-Jornet et al., 2016). Even though PGI-C has an advantage on feasibility and point out the patient-perceived impression of treatment but only 11% of BMS RCTs reported PGI-C as an outcome (Farag et al. 2019).

Up to 95% of subjects report impact problems from dental patient-reported outcome measurement (dPROMs) with a mean OHIP-5 score of 4.0 (2.3, 5.7), which was very low since the full score was 20. Therefore, the lower score of OHIP-5 defines a lower impact on OHRQoL, thus subjects seem to not be much impacted by BMS. Furthermore, when focusing on each domain of OHIP-5, orofacial pain was the most common impacted domain by 90% of the subject followed by orofacial appearance (55%). However, in 2008 Lopez-Jornet, Camacho-Alonso, and Lucero-Berdugo reported functional limitation as to the highest score among OHIP-5 subscale while other studies reported psychological discomfort (Souza et al., 2011) noted that these studies used OHIP-14 and OHIP-49 respectively. OHIP-5 is a brief and precise instrument for assessing OHRQoL. It was used in this study due to suitable for phone interviews, but it has never been used in the BMS study before.

Table 1 Sociodemographic and clinical features of primary BMS subjects against patient global impression (PGI) and oral health-related quality of life (OHRQoL)

	Frequency N (%)	PGI	OHRQoL (OHIP-5)
		Mean (95%CI)	
Age			
<65	15 (75)	2.0 (1.64, 2.36)	4.1 (2.0, 6.3)
≥65	5 (25)	2.4 (1.7, 3.1)	3.6 (-0.2, 7.4)
Working status			
Yes	14 (70)	2.1 (1.7, 2.4)	4.0 (1.6, 6.4)
No	3 (15)	2.3 (1.0, 3.8)	2.7 (1.2,4.1)
Unidentified/Prefer not to answer	3 (15)	2.0 (-0.5, 4.5)	5.3 (-2.7,13.3)
Follow-up duration			
≤12 months	8 (40)	2.4 (1.9, 2.8)	5.6 (1.9, 9.3)
>12 months	12 (60)	1.9 (1.5, 2.3)	2.9 (1.2, 4.7)
Provided BMS therapies			
Sodium Bicarbonate Mouthwash	17 (85)	2.2 (1.9, 2.5)	3.4 (2.0, 4.9)
Systemic medication	9 (45)	2 (1.3,2.7)	4.3 (0.6,8)
Topical agents	7 (35)	2.0 (1.5,2.5)	3.3 (0.7, 5.8)
Nutritional supplements	3 (15)	2.3 (0.9,3.8)	2.0 (N/A)
Others	3 (15)	2.0 (N/A)	2.3 (0.9, 3.8)
Psychological status according to HADS score			
Anxiety			
Normal	18 (90)	2.2 (1.9,2.5)	3.6 (2.2, 4.9)
Borderline	1 (5)	1.5 (-4.9, 7.9)	8.0 (-81.0, 97.0)
Abnormal/Case	1 (5)	2	15
Depression			
Normal	18 (90)	2.2 (1.9, 2.5)	3.6 (2.3, 4.9)
Borderline	2 (10)	1.5 (-4.9,7.9)	7.5 (-87.8,102.8)
Abnormal/Case	0 (0)	-	-

N/A, not applicable due to the similar score of all subjects

Besides, the mean anxiety and depression scores of 4.9 (3.8, 6.0) and 2.2 (1.1, 3.2), respectively, were within the normal range. These results were much lower than the result from the study of López-Jornet et al. in 2014 that reported mean anxiety and depression scores at 8.08 and 7.90, respectively. The cut off of anxiety and depression case in HADS were for the scores above 11 and score 8-10 was a borderline case (Braud & Boucher, 2016). Patients with a borderline score of anxiety and depression had lesser improvement and higher impact in QoL when compared with those patients who have a normal score. Due to a very low number of subjects and a few outliers, the authors could not show statistical differences.

At the time of the study, all the subjects still used at least one medication for BMS treatment. The authors did not perform statistical analysis on provided BMS therapy types because of various groups of combined treatments. The most common medication was sodium bicarbonate mouthwash (85% of subjects).

Bicarbonate is a buffer in human saliva, which reacts with acid and has a mucolytic property that can reduce saliva viscosity. Sodium bicarbonate was widely used in dentistry for routine oral care agent, prevention of dental caries and erosion, control of periodontal disease and treating the disease like oral mucositis, halitosis and also BMS. Additionally, the side effect of sodium bicarbonate was rare (Madeswaran & Jayachandran, 2018). The second common treatment was systemic medication (tricyclic antidepressants, benzodiazepines, anticonvulsants) and topical agents (topical anesthetics, moisturizer, anti-inflammatory mouthwash). Another provided treatment was occlusal polishing. However, the authors cannot conclude that the treatment result from this study was a consequence of which treatment particularly due to each subject was provided more than one treatment option. There is also a lack of studies comparing systemic and topical medications in the systematic review (McMillan et al., 2016).

A summary of the characteristics of participants against PGI-C and OHRQoL was presented in Table 1. The authors also examined the mean difference between characteristic subgroups and PGI-C and OHRQoL. However, no significant difference in PGI-C and OHRQoL between different age groups, working status, treatment options, or psychological status was found.

There are certain limitations in our study that could be considered. Firstly, this was a retrospective study and some of our subjects were elderly, so the result may have an inaccurate answer from recall bias since some questionnaires asked about past months (Choi & Pak, 2005). Second, this study was only collected the data from a one-end point without comparing it with the baseline, thus the authors cannot be certain of the actual improvement. Lastly, the authors cannot confirm that the subject understood all of the questions. Lengthy phone interviews and questionnaires could cause decision fatigue and result in irrational answers (Pignatiello, Martin, & Hickman, 2020).

To address the limitations, further studies should design as a cohort that can answer the etiology of primary BMS and confirm how early the treatment can provide substantial recovery and significantly decrease the symptoms. It would also be relevant to assess care costs for primary BMS management. It was the first survey performed in Thailand and in Southeast Asia to investigate the real impact of BMS treatments in primary BMS patients from a dental specialty clinic.

5. Conclusion

Our study suggests that primary BMS patients report large to small improvement and high quality of life status independent of different BMS treatment options. The improvement and quality of life were similar in BMS patients with a variety of follow-up durations.

The results of this study emphasize the value of OHRQoL and the patient's impression assessments to adjust strategies in managing individual primary BMS patients. Apply these instruments to primary BMS patient management may help the clinician to understand how the patient perceived the treatment.

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