

**ORIGINAL RESEARCH**

# Effect of clonazepam in the management of Burning Mouth Syndrome

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**ABSTRACT**

Clonazepam is a benzodiazepine drug used for treatment of a spectrum of disorders for example in anxiety, mood swings, sleeplessness, epilepsy, panic disorders, depression, glossodynia etc. Both topical and systemical clonazepam have been found to be effective in reducing intensity of burning sensation of oral cavity. This study was conducted on 15 subjects with oral administration of clonazepam. VAS score was used to evaluate the effects of drug. The results were statistically significant.

**Keywords:** Burning Mouth Syndrome(BMS), Visual Analogue Scale (VAS), clonazepam

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**INTRODUCTION**

Burning mouth syndrome (BMS) is defined as a burning sensation in the normal oral mucosa without any laboratory and clinical findings associated with any medical or dental condition. Burning sensations accompany many inflammatory or ulcerative diseases of the oral mucosa, but the term "burning mouth syndrome" (BMS) is reserved for describing oral burning that has no detectable cause.<sup>1,2</sup> The burning symptoms in patients with BMS do not follow anatomic pathways, there are no mucosal lesions or known neurologic disorders to explain the symptoms, and there are no characteristic laboratory abnormalities. BMS has been associated with psychological disorders in many studies. Depression is frequently associated with BMS, and in some studies, close to one-third of BMS patients have significant depression scores although, as with any chronic pain disorder, it is unclear if depression is the cause or the effect of the symptoms. Clinically, BMS can be classified into the primary and secondary forms. The primary BMS is essential or idiopathic, in which none of organic local/systemic causes can be identified, and peripheral and central neuropathies are the possible etiologies. The secondary BMS is caused by local, systemic, and/or psychological factors.<sup>3,4,5</sup>

On the other hand, it seems that pain catastrophizing is somehow more important than psychological disturbance and also sleep quality in these patients experiences. However, researches demonstrated the possibility of an association between poor sleep

quality, anxiety, depression, nutritional deficiency, hormonal imbalance, hematological disturbances and oral burning in patients with BMS.<sup>6,7</sup> Various treatment modalities have been come into existence in which a drug clonazepam is one which is usually used as a first line therapy.

**AIM**

This study was designed to investigate the effect of systemic clonazepam in order to treat the symptoms of Burning mouth syndrome.

**STUDY DESIGN**

This study was conducted in the Department of Oral Medicine and Radiology, Government Dental College Srinagar(India) in between January 2021 to November 2021. A total of 15 patients were included in the study who came with the chief complaint of oral burning. All subjects underwent a comprehensive clinical assessment, and as there were no identifiable causes of oral burning. The severity of burning will be determined using the Visual Analog Scale (VAS) and was divided into two categories: mild (0-3), moderate (4-6) and severe (7-10). Patients were instructed to take 0.5 mg clonazepam (dispersible tablets) two times a day for 15 days and also instructed to place tablet under the tongue for 2-3 minutes so as to dissolve it in the mouth and then slowly swallow. VAS values were assessed at baseline and after treatment on the 15th day. Paired t test was used to

calculated the p value before and after treatment with p value <0.05 considered to be significant.

#### INCLUSION CRITERIA

1. The inclusion criteria was established in accordance with the 2013 International Classification of Headache: intraoral burning or dysesthesia daily for > 2 h/day for > 3 months, without any clinically evident causative lesion.
2. Patients with pain not following any unilateral nerve trajectory.
3. Absence of hard and soft tissue lesions of any kind.
4. A final diagnosis was confirmed after all other possible etiologies had been ruled out.
5. All the participants should be older than 20 years.

#### EXCLUSION CRITERIA

Patients who were already consuming benzodiazepine for other cause were excluded.

#### RESULTS

The study sample was comprised of 15 patients with predominantly females with mean age of 55 years (35-75years) and reported chronic burning accompanied by oral dryness(xerostomia), tingling, and altered taste (dysgeusia) as shown in table 1 and 2. The VAS score before and after the treatment of 15 days had been recorded which is shown in table 3. Paired t test was used to calculate the p value before and after treatment which turned out extremely significant ( $p < 0.0001$ ).

**Table 1:- Gender wise distribution of burning sensation of oral cavity**

Gender	Number	Percentage (%)
Male	1	6%
Female	14	94%
Total	15	100%

**Table 2:- Distribution of various disorders accompanied with BMS**

Disorder	Number	Percentage (%)
Stress/Anxiety	12	80.0%
Altered taste	5	33.3%
Dryness of mouth (xerostomia)	3	20.0 %
Sleep disturbances	10	66.6%

**Table 3:- VAS score before (1<sup>st</sup> day) and after treatment (15<sup>th</sup> day)**

Visit	VAS (0-9)	Number	Percentage	Mean VAS	t value	P value
1 <sup>st</sup>	Mild (0-3)	2	13	6.60(±0.99)	28.5173	0.0001
	Moderate (4-6)	6	40			
	Severe (7-10)	7	47			
2 <sup>nd</sup>	Mild (0-3)	10	67	1.06(±0.6)		
	Moderate (4-6)	4	27			
	Severe (7-10)	1	6			

#### DISCUSSION

BMS has been divided into two types, thus primary (there is no other disease) and secondary (possibly attributable to a local or systemic disorder). Primary BMS is idiopathic, in that the organic local/systemic causes cannot be identified.<sup>1</sup>

In our study, statistically significant results were found out before and after a 15 days treatment of clonazepam therapy with a great degree of decreasing mean VAS score after 15 days of administration of the drug. Optimal administration route for clonazepam in BMS patients has been explored by many studies. Some studies administered topically clonazepam while other tried systemic administration. A few studies on topical clonazepam demonstrated both significantly decreased pain scores and improvement of pain/ burning symptoms in BMS patients.<sup>8,9</sup> Rodriguez et al. conducted a detailed study and provide analysis of all 66 patients, including a gradual increase in clonazepam dosage and a placebo

group were included in order to compare the data to that of the treatment group, and affirmed the benefit of the medication.<sup>9</sup>

GrushkaM et al performed a study on BMS and presented a consistent pain reduction in systemic clonazepam treatment.<sup>10</sup> Amos et al. explored combined administration methods i.e. topical as well as systemic route of administration and their pharmacological effect,. This study found that intraoral clonazepam was superior to oral ingestion; pain was much more rapidly alleviated but the duration of action was reduced.<sup>11</sup> Studies have been conducted by Liu YF et al, Cinar S et al and Heckmann SM et al on the pharmacological treatment of BMS including clonazepam therapy, which have been found out that clonazepam demonstration showing promising therapeutic effects.<sup>12,13,14</sup>

## CONCLUSION

The study was done in order to predict the therapeutic outcomes of clonazepam in the treatment of burning mouth syndrome. In our study promising results were seen and relief of symptoms are significantly seen after treatment.

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