

**THE UNIVERSITY OF MEDICINE AND PHARMACY  
"CAROL DAVILA", BUCHAREST  
DOCTORAL SCHOOL  
THE FIELD OF MEDICINE**

**SUMMARY  
PhD THESIS**

**PhD supervisor:**

**PROF. UNIV. DR. BOGDAN OVIDIU POPESCU**

**PhD student:**

**DUGAN COSMIN-DRAGOȘ**

**2024**

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**SUMMARY**

**Clinical and imaging aspects in burning mouth  
syndrome**

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### **The importance of the topic**

Burning mouth syndrome (BMS) represents a pathological entity that is little known and understood except for the dental profession and possibly, the specialty of neurology. This aspect, common in most European countries, is one of the reasons that determine a complicated route (6-10 visits to doctors with different specialties) and prolonged (6 months-2 years) for patients with this affliction.

Another aspect that represents a difficulty in achieving a rapid diagnosis is the nociplastic nature of the pain sensations found in BMS. The lack of local objective manifestations, along with the presence in most cases of comorbidities and poly medication in patients with persistent non-specific oral pain, are important causes of delay in diagnosis and evaluation by an oral pathology specialist or an experienced neurologist.

### **The motivation for choosing the research topic**

A first reason for choosing this research topic is the fact that BMS represents an underdiagnosed and undertreated pathology in Romania. I believe that any contribution and scientific collaboration within this niche can contribute to a better understanding of the needs of BMS patients and improve the diagnostic and treatment conditions that can be offered by the national health services.

The need for an interdisciplinary approach to the patient with burning mouth syndrome was another important reason behind the choice of this field of research. Patients with burning mouth syndrome require an integrated approach in all stages of the disease, especially in resistant cases or with multiple associated comorbidities. Therapeutic success is dependent on the existence of a dedicated human and medical infrastructure, specialized and interconnected with other international centers of expertise.

### **Study objectives**

The main purpose of the research is the multidimensional profiling (demographic, sociological, psychological, clinical, biological, imaging) of a representative sample of Romanian patients diagnosed with burning mouth syndrome by the medical doctors from the Oral Pathology service of the Faculty of Dentistry within the University of Medicine and Pharmacy "Carol Davila" Bucharest, between 2018-2022. The result of this research consists in identifying the most effective clinical tools necessary for the diagnosis, stratification and monitoring of patients with burning mouth syndrome, to be included in a work protocol that will serve as a completely useful decision support for multidisciplinary medical teams.

The secondary objectives of the study consider the development of a muscle-computer interface concept at a technological maturity level (TRL – technology readiness levels) 2, which could be used for the monitoring and evaluation of several oral pathologies.

### **Study protocol**

The study carried out is a prospective, observational longitudinal and comparative one and includes a sample of 120 patients initially diagnosed with burning mouth syndrome by medical doctors from the Department of Oral Medicine, Faculty of Dental Medicine, "Carol Davila" University of Medicine and Pharmacy. The enrollment period in the study was June 2018-March 2022. The control group (CTRL) was represented by dental patients and from the internal medicine and surgery services, without specific symptoms of burning mouth syndrome, who were standardized according to age and sex with the BMS patient group. All study participants gave written informed consent.

The diagnosis of BMS was made according to the recommendations of the WHO (World Health Organization, 2023) and the International Headache Society (Headache Classification Committee of the International Headache Society, 2018).

#### Performing clinical-functional investigations

For the selected group of patients, the following were performed:

- obtaining anamnestic data
- examination of the oral cavity
- objective examination (outside the oral cavity)
- carrying out tests, scores, standardized questionnaires
- collection of biological samples
- imaging examination (selective) which involved computer tomography and magnetic resonance
- tongue biopsy and saliva sampling (14 cases)
- other types of investigations such as electrocardiogram and abdominal ultrasound
- other specialist consultations, depending on comorbidities (optional)

For each participant, socio-demographic data (age, sex, education, BMI, employment, marital status and use of e-mail, smartphones and social networks), lifestyle and habits (tobacco consumption, alcohol, coffee and of carbonated drinks, as well as the type of diet and contact with animals – domestic, pet) were recorded.

## **Patient monitoring**

Patient monitoring was carried out over a period of minimum 12 months and maximum 30 months, the variations being determined by the degree of compliance of the patients and especially by the reaction determined by the COVID19 pandemic and the restrictions imposed.

Monitoring consisted of: oral cavity examination (one year or as needed); carrying out tests, scores, standardized questionnaires; collection of biological samples (selected patients, for example with nutritional deficiencies who have received therapeutic guidance); other specialist consultations, depending on comorbidities (optional).

## **Data collection and validation**

It was carried out throughout the duration of the study. This stage was correlated with the sub-stages of carrying out clinical-biological investigations, imaging and monitoring of the study group and the control group. At the end of the study, the correctness of the information contained in the observation sheets and survey sheets from the study with those in the electronic files was verified.

## **Statistical analysis**

It was performed using IBM SPSS v25. All variables were summed with descriptive statistics such as means, standard deviations, and frequencies. Differences between groups were assessed using the Chi-square test and two-sample t test for categorical and continuous variables, respectively. Correlations between continuous variables were performed using the Pearson test.

**Student's t-test** (t-test), analysis of variance (ANOVA), and analysis of covariance (ANCOVA) are statistical procedures used in hypothesis testing for comparing mean differences between groups. The test variable (dependent variable) should be continuous-scale and approximately normally distributed for these approaches.

The **Chi-square test** (also known as the Pearson Chi-square test) is a useful statistical method for evaluating hypotheses when variables are nominal, a common feature in clinical research. The chi-square test is one of the most well-known and used to analyze nominal or qualitative variables, i.e. to determine the existence or not of independence between two variables. Unlike other statistics, Chi-square can provide information not only on the significance of any observed differences, but also on the categories that explain any disparities discovered.

### **Longitudinal evaluation of the population of patients with non-specific oral pain and stratification according to sex, age categories and duration of symptoms**

The association of sleep disorders with the persistence and intensity of burning mouth syndrome symptoms raises the question of direct causality or a combination of common risk factors for both pathologies. Similarly, it is unclear to what extent persistent BMS symptomatology is associated in women with other more commonly described postmenopausal pathologies, such as fibromyalgia, restless legs syndrome, or chronic fatigue syndrome.

We believe that the role of educational level, as well as that of digital literacy, is important both as a prognostic factor and for response to therapy. In our study, the educational level of patients with non-specific oral pain was high, most of them having university education. This characteristic influences the ability of patients to understand the disease, the way of reporting the symptoms, the forms of manifestation of the anxiety-depressive disorder or the possibility of using therapeutic tools such as psychotherapy or the use of telemedicine solutions.

### **Case-control evaluation of some socio-demographic, clinical and biological parameters in patients with non-specific oral pain versus patients without non-specific oral pain**

The correlation between the higher prevalence of hypertension in patients with BMS vs CTRL opens an important line of research, very little investigated to date, which could have a major impact on the quality of life and possibly survival of these patients. The causal relationships between cardiovascular and cardiometabolic comorbidities and chronic nociceptive pain syndrome localized from primary glossodynia is a research topic, with echoes for other similar pathologies such as other oro-facial pain, fibromyalgia, nociceptive neuropathies.

Similarly, the much higher prevalence of *H. pylori* infections in patients with burning mouth syndrome, along with other digestive manifestations, recommends a gastroenterology consultation in these patients, after diagnosis.

### **Comparative evaluation of some imaging aspects in patients with non-specific oral pain versus patients without non-specific oral pain**

In order to clarify the role of neuroimaging in the case of this suffering, we believe that it is necessary to carry out more extensive studies, comparisons with other neurological pathologies or pain syndromes and the integration of these data, including the use of



advanced machine-learning (ML) solutions for data stratification and analysis. As a conclusion of this arm of the study, we believe that neuroimaging methods are important both for the diagnosis of certainty and patient monitoring, and for the creation of a standardized database to serve a national registry of orofacial pain syndromes.

### **Comparative evaluation of some neuropsychological parameters (stress, depression, sleep disorders and verbal fluency disorders) in patients with non-specific oral pain versus patients without non-specific oral pain**

Our data, showing impairments related to quality of life, high levels of stress and depression, as well as sleep disturbances and verbal fluency disorders, highlight that patients with non-specific oral algia require specific assistance with a predilection for psychological, psychiatric and neurological problems.

A conclusion that is imposed on the basis of this study, supported also by the data from the literature, emphasizes the importance of a multidisciplinary approach to BMS, an aspect that involves a close collaboration between dentists, clinical psychologists and psychiatrists, etc. This collaboration is necessary both for the realization of a complete diagnosis and staging, as well as for the integrated therapeutic approach.

### **Prevalence of non-communicable diseases and main associated risk factors in patients with primary BMS**

Our study, which shows that BMS in the studied Romanian population is significantly associated with cardiovascular diseases, arterial hypertension and dyslipidemia, emphasizes that a multidisciplinary clinical approach, which also includes a cardiovascular and metabolic evaluation, is essential for the successful management of the patient with BMS. Moreover, our results highlighted the importance of an integrated NCD prevention and care strategy in the BMS population. We believe that further studies are needed to better understand the association between NCD and BMS.

### **Comparative study on the psychological impact of SARS-CoV-2 infection in patients with non-specific oral pain**

In patients with burning mouth syndrome with coronavirus infection, there was a more pronounced increase in anxiety-depressive symptoms in the first 6 months after infection, followed by a decrease in symptom intensity compared to the initial examination.

Oral symptoms had a similar evolution, their intensity was determined by the severity of the episode of infection with COVID-19 and the prolonged use of antivirals.

We believe that the decrease in symptoms observed after the first 6 months is due to both psychological factors, intrinsic and dependent on the evolution and societal response to the COVID19 pandemic, as well as factors related to the improvement of the quality of patient care, after the episode of coronavirus infection.

A number of individual factors affected the psychological response to the risk of infection, the infection itself and the lockdown measures, an aspect that requires a detailed psychological and sociological evaluation of the participants in similar studies.

### **Final conclusions**

We believe that the multi-perspective approach carried out in our research has primarily allowed us to evaluate the patient with BMS beyond the herald of this pathology - facial pain syndrome and to integrate intricate aspects of etiopathogenesis, therapy and quality of life in these patients. Thus, associations were identified in these patients between the intensity and persistence of non-specific oral pain and sleep disorders, the prevalence of arterial hypertension, *Helicobacter pylori* infection, previous exposure to occupational toxins and environmental pollution, as well as the increased prevalence of non-communicable diseases in general (especially cardiovascular, metabolic, psychiatric, dental and neurological), compared to the control group, in patients with non-specific oral pain.

Our research emphasizes the importance of detailed and repeated neurological and psychiatric evaluations, given both the more frequent personal history of pathology and the increased prevalence of risk factors. Gastroenterological evaluation also plays a significant role, currently ignored, although patients with facial algae repeatedly arrive at the services of this specialty and present multiple digestive ailments. We also emphasize the importance of a nutritional strategy for patients with oral-facial algae.

Starting from these conclusions of our research, we propose the establishment in Romania of a National Association for the study of oro-facial algae and a National Register of Oro-Facial Algae. In addition to this approach, we believe that it is also necessary to create an Association of patients with Oro-Facial Algae, which would contribute synergistically through information and education programs for patients, the running of counseling programs and free psychological assistance, the creation of support groups with patients with persistent forms, advocacy and fundraising.

Among the non-pharmacological therapies of interest, in particular non-invasive transcranial stimulation (magnetic, electrical, possibly also with low-power laser), has a little explored potential in the case of orofacial algia therapy. Similarly, feedback-based therapies (biofeed-back, EEG neurofeedback) are accessible and very little used, although they have demonstrated some therapeutic effects in other pain syndromes. The potential of psychological services (psychotherapy, occupational therapy) and some complementary therapies (animal-assisted therapy), we also consider that they are underestimated in the therapeutic arsenal of patients with non-specific oral pain associated with various psychiatric disorders.

The limitations of this study consisted in the fact that it was unicentric, the period of implementation was relatively short and marked by the significant impact produced by the COVID-19 pandemic. Other limitations stemmed from limited access to some resources – for example, the ability to perform multiple neuroimaging investigations performed on both groups of patients. A series of statistical patterns of interest, not anticipated at the time of the study, became evident late and did not allow for more detailed investigations (e.g. aspects related to lifestyle or cardiovascular pathologies).

However, we believe that the originally proposed scientific research objectives have been achieved.

### **Personal contributions**

As part of our research, we created one of the most complex databases for patients with burning mouth syndrome in Romania, for each investigated patient there are 12 sectors of interest, which in total include a maximum number of 200 descriptive parameters. Considering the diversity and complexity of the analyzes performed, we would like to propose that this database model be used to create a national registry for facial algia.

From the research carried out, a number of original aspects emerged, such as the statistically significant higher prevalence of hypertension, *Helicobacter pylori* infection, sleep disorders and previous exposure to occupational toxicants and environmental pollution, as well as the prevalence of non-communicable diseases, compared with the control group, in patients with non-specific oral pain.

Another element of originality of the work consists in highlighting the impairment of verbal fluency in patients with BMS over 60 years old and normal from a cognitive point of view. In the case of correlating the semantic and phonetic scores of BMS patients with those obtained in the other neuropsychological tests, it was found that verbal tasks correlate

with perceived stress, depressive symptoms and sleep quality, suggesting that this impairment may be a consequence of the general psychological distress that characterizes BMS patients. A complement to this discovery envisages the use of methods such as reaction time (RT) or choice reaction time (CRT) testing - onsite or via telemedicine - for further stratification of patients with neuropathic pain syndrome.

Researching the prevalence of non-communicable diseases and their main risk factors in patients diagnosed with non-specific oral pain and with a chronological age over 50 years represents another original approach of our study.

Moreover, to our knowledge, this is the largest study in terms of cohort size and number of assessed characteristics (lifestyle habits, quality of life data, stress, depression and anxiety, sleep quality, and cognitive functions) conducted on Eastern European BMS patients.

Also in the research, we reported, in an exploratory study, a higher prevalence of imaging signs of leukoaraiosis, with moderate changes being more frequent among patients with BMS. Due to the small number of patients who underwent brain imaging (CT or MRI), these observations do not reach a statistically significant threshold in our research.

Another original research is the longitudinal study that evaluated changes in depressive and anxiety symptoms in patients with burning mouth syndrome during the COVID-19 pandemic, as well as evaluating the effect of SARS-CoV-2 infection on these psychological symptoms, comparing patients with burning mouth syndrome infected (COVID+) with a group of non-infected burning mouth syndrome patients (COVID-).

Another original approach that resulted from our research resulted in the publication of the first article dedicated to the medico-legal and ethical aspects associated with the diagnosis, treatment and research of patients with BMS.

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## List of published scientific papers

### Articles published in ISI and PubMed indexed journals

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## Oral scientific communications with abstract published in conference volumes

**C. Dugan** Dinculescu, C. Vizitiu and I. Pârlătescu. **A. Study on Choice Reaction Time as a Complementary Method in Idiopathic Orofacial Pain.** 2021 International Conference on e-Health and Bioengineering (EHB), 2021, pp. 1-4, doi: 10.1109/EHB52898.2021.9657580.

**C. Dugan**, I. Pârlătescu, A. Dinculescu and C. Vizitiu. *Therapeutic Potential of Noninvasive Transcranial Magnetic Stimulation in Burning Mouth Syndrome.* 2021. International Conference on e-Health and Bioengineering (EHB), 2021, pp. 1-4, doi: 10.1109/EHB52898.2021.9657555.

Elena Milanesi, **Cosmin Dugan**, Maria Dobre, Ioana Andreea Musat, Serban Tovar, Ioanina Pârlătescu “*Neuropsychological features of patients with burning mouth syndrome*” 5th Congress of Psychiatry of Bosnia and Herzegovina-Psychiatry in the Changing World, Mostar, Bosnia și Hertegovina (4-6 November, 2022).

**Cosmin Dugan.** *The value of brain imaging (MRI) in the diagnosis and prognosis of burning mouth syndrome.* Simpozionul anual 2022 al Societății Române de Medicină Orală, 28 Mai 2022, București.

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## Projects

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