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Evaluation of a Protocol For Topical Application of Capsaicine Gel 0.025 % in the Management of Burning Mouth Syndrome Correlating its Impact on Quality of Life

Evaluación de un Protocolo de Aplicación Tópica de Capsaicina Gel 0,025 % en el Tratamiento del Síndrome de Boca Ardiente Correlacionando su Impacto con la Calidad de Vida

Carla Militão Ricken; Silvia Natalia Souza de Péder; Daniela Suemi Kamikawa; Neli Pieralisi; Mariliani Chicarelli & Elen de Souza Tolentino

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ABSTRACT: The aim of this study is to report the results obtained with a protocol of topical application of capsaicin gel 0.025 % in the management of burning mouth syndrome (BMS) to evaluate the influence of the disease and treatment on their quality of life (QOL) using the OHIP-14 questionnaire (Oral Health Impact Profile). After clinical examination and diagnosis of BMS, 10 patients reported the intensity of the burning by means of a subjective score ranging from 0 to 10 and also answered the OHIP-14. Then, a topical application protocol of capsaicin gel 0.025 % was initiated, with weaning from medication and complete withdrawal within 180 days. At each reassessment consultation (30, 60, 90 and 180 days), the patients answered the OHIP-14 and subjective burning scores were collected again. Overall, the capsaicin gel showed gradual reduction or elimination of symptoms of BMS, as well as an improvement in the QOL of patients throughout treatment. At 180 days, after medication withdrawal, 6 patients (60 %) reported total absence of burning and in four patients (40 %) the score remained or decreased. In one patient (10 %) the score increased, although it remained below the initial score. The results showed an improvement in the QOL of all patients who completed the protocol and the impact of BMS on the QOL decreased in relation to the initial score in all patients. The topical use of 0.025 % capsaicin gel was effective in reducing or remitting symptoms of BMS. The OHIP-14 questionnaire showed the negative impact of BMS on patients' QOL and the role of treatment in its improvement.

KEY WORDS: Burning mouth syndrome, capsaicin, quality of life.

INTRODUCTION

Burning Mouth Syndrome (BMS) is a chronic condition characterized by a burning sensation in the oral cavity without an obvious cause or the presence of lesions on physical examination. It mainly affects menopausal and post-menopausal women (Currie & Jääskeläinen, 2020; Paudel *et al*., 2020). The International Association for Study of Pain defines the BMS as a chronic intraoral burning sensation in which there are no identifiable systemic or local causes (Burning Mouth Syndrome, 2016). The etiology is not yet fully elucidated; however, it is known that it is complex and multifactorial, involving the interaction between neurophysiological mechanisms and psychological factors (Aravindhan *et al*., 2014; Currie & Jääskeläinen).

BMS can be classified into three types according to the intensity and duration of the burning symptoms. In Type 1, patients wake up without any symptoms, but the pain increases throughout the day and is greater at night. This type affects 35 % of patients with BMS and is associated with nutritional deficiencies, diabetes mellitus and autoimmune diseases. Type 2 is the most common, affecting 55 % of patients. It is

Department of Dentistry, State University of Maringá, Maringá-PR, Brazil.

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characterized by the presence of symptoms continuously throughout the day and is related to psychological disorders. Patients still report sleeping difficulties. In Type 3, there is pain at intervals varying with pain-free periods. It affects 10 % of patients and is related to allergic reactions (Sun *et al*., 2013; Coculescu *et al*., 2014; Kisely *et al*., 2016).

Due to the fact that BMS has a complex and idiopathic behavior, many drugs have been proposed for its management, and the correct clinical diagnosis is extremely important to define the treatment. Therapy involves systemic and/or topical medications (Aravindhan *et al*.). Among the systemic drugs are clonazepam, tricyclic antidepressants, selective serotonin reception inhibitors, antipsychotics, hormone replacement in cases of postmenopausal women, vitamin supplementation in addition to cognitive-behavioral therapy (Aravindhan *et al*.; Sun *et al*.). Among topical medications, capsaicin gel, Aloe vera, lidocaine and clonazepam have been proposed (Sun *et al*.).

Capsaicin, present in many types of pepper, is an analgesic indicated for neuralgia, osteoarthritis, rheumatoid arthritis, diabetic neuropathy and pruritus and, although its action is not fully elucidated, studies demonstrate a variable reduction of symptoms when applied daily three to four times on the mucosa (Montadon *et al*., 2011). The patient should be alerted that the capsaicin may cause an increased burning sensation immediately after application (Currie & Jääskeläinen). This initial increase in burning occurs because capsaicin binds to nociceptors, specifically the TRPV1 receptor (potential transient receptor vaniloid 1), located mainly in the polymodal C fibers, which causes an initial neuronal excitation and release of pro-inflammatory mediators followed by hyperalgesia (Jørgensen & Pedersen, 2016). The repeated application causes prolonged activation of the TRPV1 receptor, resulting in loss of its functionality and impairing local nociception for prolonged periods (Anand & Bley, 2011; Jørgensen & Pedersen). Receptor defunctionalization occurs due to temporary loss of membrane potential, inability to transport neurotrophic factors leading to altered phenotype and reversible retraction of the terminals of the epidermal and dermal nerve fibers (Anand & Bley). Thus, capsaicin has been considered a potential treatment option in patients with BMS (Jørgensen & Pedersen). The systemic use of capsaicin is also documented. However, reports of effects such as dyspepsia are frequent (Kisely *et al*.).

The assessment of quality of life (QOL) aims to understand how different domains are influenced by the characteristics of changes (diseases) that affect the individual (Afonso *et al*., 2017). According to Kolkka *et al*. (2019) and López-Jornet *et al*. (2008), BMS can have a negative impact on the patient's general and psychological well-being and can affect QOL (López-Jornet *et al*.; Kolkka *et al*.). Knowing the psychosocial aspects related to oral health problems, Slade (1997) formulated a questionnaire named “Oral Health Impact Profile” - OHIP-14, which aims to measure dysfunction, discomfort and disability attributed to the condition allowing, in a single administration, collect information about severity, extent and prevalence of negative impacts of oral health status on people's QOL (Slade, 1997). It is one of the most widely used international indicators to assess QOL with good psychometric qualities and that allows measuring self-perception of the consequences inherent to oral conditions (Afonso *et al*.). The questionnaire has 14 questions grouped in seven dimensions: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and disability (De Oliveira & Nadanovsky, 2005). It was mentioned as an instrument of high precision and reliability, being very useful for clinical use (De Oliveira & Nadanovsky; Liu *et al*., 2012).

Considering that BMS is a multifactorial dysfunction and that treatment is challenging, the aim of the present study is to report the results obtained with a protocol of topical application of capsaicin gel 0.025 % in the management of BMS and to evaluate the influence of the disease and the treatment in the QOL of patients using the OHIP-14 questionnaire.

MATERIAL AND METHOD

This research was approved by the Ethics Committee in Research with Human Beings of the State University of Maringá (UEM) (CAAE: 66087717.7.0000.0104) and all patients signed the free and informed consent form. The sample consisted of 18 patients in the period from 2017 to 2019. Sex, age, marital status and ethnicity data were collected. Patients allergic to pepper or any constituents of the formula were excluded, as well as continuous users of tricyclic antidepressant drugs and clonazepan.

After clinical examination and diagnosis of BMS, these patients underwent a more in-depth anamnesis with psychological issues, presence of xerostomia, use

of medications and possible causal factors. The patient reported the intensity of the burning by means of a subjective score ranging from 0 to 10, where 0 was symptom-free, 5 corresponded to bearable symptoms and 10 to unbearable burning (Péder *et al*., 2018).

Even at the first consultation, the patient answered the OHIP-14 questionnaire, with the 14 questions in seven dimensions organized so that the participant indicated how often they experienced each problem within a reference period, using a Likert-type scale with five categories of responses: Very often = 4; Fairly often = 3; Occasionally = 2; Hardly ever = 1; Never = 0 (De Oliveira & Nadanovsky). For each question, their weight was divided by four (which is the number of possible answers because "never" is equal to zero) (Table I). The additive method was used to obtain the final score in OHIP-14, as it allows assessing the severity of the impact, with higher scores indicating a poorer QOL (Slade). The questionnaires were applied by the same previously calibrated researcher, who asked the questions.

After this procedure at the initial consultation, a topical application protocol of capsaicin gel at a concentration of 0.025 % was initiated as follows (Péder *et al*.):

- Application of the gel (in the burning region) 3 times a day for 1 month;
- Reassessment - 30 days;
- Application 2 times a day, alternating the days (every other day) for 1 month;
- Reassessment - 60 days;
- Application 1 time a day, 3 times a week for 1 month;
- Reassessment - 90 days;
- Complete removal of the gel;
- Reassessment - 180 days.

The patients were instructed not to swallow the gel and perform the application after adequate oral hygiene.

At each reassessment consultation (30, 60, 90 and 180 days), the patients answered the OHIP-14 questionnaire again and subjective burning scores were collected.

RESULTS

Eighteen patients with BMS were evaluated. All were women, aged between 30 and 69 years. Sixteen (88.8 %) patients had depression, anxiety and/or stress. Seven (38.8 %) patients reported xerostomia associated with burning mouth, and the feeling of dry mouth increased as stress and burning increased.

All patients started the protocol. However, six (33.3 %) abandoned the treatment after observing

Table I. Dimensions, questions and weights of the OHIP-14 questionnaire.

Dimension	Question	Weight
Functional limitation	Have you had trouble pronoucing any words because of problems with your teeth, mouth or dentures?	0.51
	Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?	0.49
Physical pain	Have you had painful aching in your mouth?	0.34
	Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?	0.66
Psychological discomfort	Have you been self-conscious because of your teeth, mouth or dentures?	0.45
	Have you felt tense because of problems with your teeth, mouth or dentures?	0.55
Physical disability	Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	0.52
	Have you had to interrupt meals because of problems with your teeth, mouth or dentures?	0.48
Psychological disability	Have you found it difficult to relax because of problems with your teeth, mouth or dentures?	0.60
	Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	0.40
Social disability	Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?	0.62
	Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?	0.38
Handicap	Have you felt that life in general was less satisfying because of problems with your teeth, motith or dentures?	0.59
	Have you been totally unable to funtion because of problems wilh your teeth, mouth or dentures?	0.41

Source: Slade, 1997.

improvement in the first reevaluation (30 days) and two (11.1 %) reported some reaction to the medication, such as erythema on the lip and jugal mucosa, therefore being excluded from the sample. Thus, 10 patients who completed treatment were included in this study. In these patients, the initial burning scores ranged from 5 to 10. In the 30-day reassessment, all patients reported some improvement, with scores ranging from 0 to 8. This improvement was repeated in the controls of 60 (scores 0 to 5) and 90 days (scores 0 and 5). At 90 days, five patients (50 %) reported total absence of symptoms and four (40 %) reported significant improvement (scores 0 to 2). In only one patient, the score (5) remained in the consultations for 30, 60 and 90 days. In the last evaluation, at 180 days, after medication withdrawal, six patients (60 %) reported total absence of burning, in four patients (40 %) the score remained or decreased. In one patient (10 %) the score increased, although it remained below the initial score (Table II).

As for the OHIP-14 questionnaire, the results showed an improvement in the QOL of all patients who completed the protocol, as shown in Table III. The impact of burning mouth on the QOL decreased in relation to the initial score in all patients.

Table II. Burning scale (subjective scores) in the periods of the protocol.

Patient	*Subjective burning scores*				
	Initial	30 days	60 days	90 days	180 days
1	9	6	4	2	2
2	10	7	4	0	0
3	6	3	0	0	0
4	10	8	5	2	2
5	8	4	0	0	0
6	6	3	0	2	0
7	8	6	3	1	2
8	7	5	5	5	3
9	5	0	0	0	0
10	5	1	0	0	0

Table III. Impact on patients' quality of life according to the OHIP-14 questionnaire.

Patient	*Impact of burning on quality of life*				
	Initial	30 days	60 days	90 days	180 days
1	3.39	1.52	0.16	0.08	0.08
2	5.2	3.97	2.08	0.84	0
3	3.02	1.56	0.77	0	0
4	5.12	4.2	2.99	0.84	0.3
5	3.81	1.81	0	0	0
6	5.23	2.74	0.12	1.08	0
7	3.82	5.37	4.1	1.22	0.95
8	4.78	3.35	0.28	0.22	0.22
9	2.14	0	0	0	0
10	5.99	4.78	0.36	0	0

The reference value is 7 (total sum of the weights of the questions in the OHIP-14 questionnaire).

DISCUSSION

BMS is a chronic debilitating orofacial pain, defined by a burning sensation of the oral mucosa, without identifiable oral lesions or related laboratory findings (Grushka *et al*., 2002; Forssell *et al*., 2020). In the present study, all patients were women over 30 years old, corroborating the literature (Acharya *et al*., 2018). According to Acharya *et al*., BMS is more common in women than men, affecting mainly those in the peri and post-menopausal period. Psychological factors such as stress, depression and anxiety are often involved (Acharya *et al*.), reaffirming that BMS has a multifactorial nature and several factors must be investigated for the diagnosis.

In the present study, 38.8 % of patients had associated xerostomia. Dysfunction of the salivary glands can influence BMS, as it leads to hyposalivation, dryness of the oral mucosa, pain and discomfort (Acharya *et al*; Lamey & Lamb, 1988). These patients also reported that the sensation of dry mouth tended to increase in episodes of burning and stress. Thus, we speculate whether stress and burning can directly contribute to elevating the feeling of dry mouth. According to Aravindhan *et al*., changes in taste and xerostomia may be associated with BMS (Aravindhan *et al*.).

The OHIP-14 showed that, before the start of treatment, patients had complaints that directly affected their QOL but that, with the establishment of the protocol, there was a gradual improvement in this aspect, indicating that BMS negatively influences QOL patients, corroborating the literature (Kolkka *et al*.; López-Jornet *et al*.; Péder *et al*.).

In this study, the topical application of capsaicin gel 0.025 % reduced the intensity of oral burning in all patients, preventing them from being subjected to systemic treatments. It was believed that the capsaicin pain relief mechanism occurred

through the local reduction of substance P, considered the main responsible for the transmission of peripheral painful impulses to the central nervous system (Jørgensen & Pedersen; Monteiro *et al*., 2011). However, some studies suggest that the decrease in substance P has little or no role in pain relief. Instead, capsaicin would have a mechanism of action best described as nociceptor "defunctionalization" (Anand & Bley; Jørgensen & Pedersen).

According to Gleber Netto *et al*. (2010), the systemic use of capsaicin 0.25 % (orally for one month) reduced the burning symptoms; however, there was gastric discomfort that progressively increased with the course of treatment (Gleber Netto *et al*.). Sun *et al*. reported that topical capsaicin can be used as a desensitizing or analgesic agent to treat BMS; however, the bitter taste and the increased burning sensation at the beginning of the treatment may hinder the acceptance (Sun *et al*.). Despite being reported in the literature, the sensation of heat, initial burning and bitter taste of capsaicin did not represent a reason for giving up treatment in this study and patients reported getting used to the gel quickly. For Monteiro *et al*. being topical and therefore considered a conservative treatment, capsaicin gel is the most suitable treatment for BMS (Monteiro *et al*.). The main contraindication is allergy to pepper (Elitt *et al*., 2008). For this reason, two patients were excluded from our sample.

The diagnosis of BMS depends on a careful clinical examination and the exclusion of other local and systemic factors that can cause secondary burning in the oral mucosa (Kolkka *et al*.; Oliveira *et al*., 2013). Due to its complex and multifactorial etiology, the management is challenging, and the disease requires a systematic and interdisciplinary approach, with an individualized treatment planning (Aravindhan *et al*.; Currie & Jääskeläinen). Obtaining a complete history of pain characteristics, examining the oral mucosa, assessing systemic condition and associated psychological factors contribute to the correct diagnosis of BMS. Allergy, gastric reflux and viral, bacterial or fungal diseases should be excluded from possible causes of burning (Aravindhan *et al*.). The patient must be informed about the difficulty of obtaining results and the importance of the cooperation with the treatment, which can be long, avoiding misinformation, which causes irritability and anxiety, aggravating the symptoms. In addition, the clinician must offer support and demonstrate confidence in conducting treatment, always aiming at the patient's best QOL (Oliveira *et al*.).

CONCLUSION

The topical use of 0.025 % capsaicin gel according to the proposed protocol was effective in reducing or remitting symptoms of BMS. Additionally, the application of the OHIP-14 questionnaire showed the negative impact of BMS on patients' QOL, as well as the role of treatment in its improvement.

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RESUMEN: El objetivo de este estudio fue reportar los resultados obtenidos con un protocolo de aplicación tópica de gel de capsaicina al 0,025 % en el manejo del síndrome de boca ardiente (SBA), para evaluar la influencia de la enfermedad y el tratamiento en su calidad de vida (CV) mediante el cuestionario OHIP-14. Tras el examen clínico y diagnóstico de SBA, 10 pacientes refirieron la intensidad del ardor mediante una puntuación subjetiva de 0 a 10 y también respondieron la OHIP-14. Luego, se inició un protocolo de aplicación tópica de gel de capsaicina al 0,025 %, con destete de la medicación y retiro completo en 180 días. En cada consulta de reevaluación (30, 60, 90 y 180 días), los pacientes respondieron el OHIP-14 y se recogieron nuevamente las puntuaciones subjetivas de quemado. En general, el gel de capsaicina mostró una reducción o eliminación gradual de los síntomas del SBA, así como una mejora en la calidad de vida de los pacientes durante todo el tratamiento. A los 180 días, después de la retirada de la medicación, 6 pacientes (60 %) informaron ausencia total de ardor y en cuatro pacientes (40 %) la puntuación se mantuvo o disminuyó. En un paciente (10 %) la puntuación aumentó, aunque se mantuvo por debajo de la puntuación inicial. Los resultados mostraron una mejora en la CV de todos los pacientes que completaron el protocolo y el impacto de SBA en la CV disminuyó en relación con la puntuación inicial en todos los pacientes. El uso tópico de gel de capsaicina al 0,025 % fue efectivo para reducir o remitir los síntomas del SBA. El cuestionario OHIP-14 mostró el impacto negativo de SBA en la CV de los pacientes y el papel del tratamiento en su mejora.

PALABRAS CLAVE: Síndrome de boca ardiente, capsaicina, calidad de vida.

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Corresponding author:
Carla M. Ricken
Graduanda do 5° ano do Curso de Odontologia - UEM
Integrante bolsista do Grupo PET - Odontologia
Monitora de Cirurgia
Maringá/PR
BRASIL

E-mail: carlaricken@gmail.com