# A systematic review of acupuncture or acupoint injection for management of burning mouth syndrome

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Objective: Burning mouth syndrome (BMS) is a common chronic pain condition that lacks a satisfactory treatment approach. This systematic review was designed to examine the effects of acupuncture or acupoint injection on the management of BMS and to evaluate the evidence supporting the use of acupuncture therapy for BMS in clinical practice. Method and Materials: The following databases were searched for relevant articles: Cochrane Oral Health Group Trials Register (July 2011), Cochrane Central Register of Controlled Trials (issue 7, 2011), MEDLINE (1966 to June 2011), and electronic medical database from the China-National Knowledge Infrastructure (1979 to June 2011). Articles were screened, and the quality of the included trials was assessed independently by two reviewers. Results: After screening, nine studies with 547 randomized patients were included in this review. All nine articles were published in Chinese and were clinical trial studies with a Jadad score < 3. Their results showed that acupuncture/ acupoint injection may benefit patients with BMS. The evidence supported the efficacy of acupuncture/acupoint injection therapy in reducing BMS pain and related symptoms. Conclusion: In light of the positive outcomes reported, the use of acupuncture therapy for BMS patients warrants further research. (Quintessence Int 2012;42:695-701)

Key words: acupoint, acupuncture, burning mouth syndrome, pain, therapy

Burning mouth syndrome (BMS) is a chronic pain condition characterized by pain or a burning sensation affecting the oral mucosa in the absence of visible abnormality. The International Association for the Study of Pain and International Headache Society define it as a distinctive nosological entity and a pain of at least 4 to 6 months duration on the tongue or other mucosal membranes in the absence of clinical or laboratory findings. In the general population, the prevalence of BMS ranges from 0.7% to 15% and is more common in women, particularly after menopause.<sup>1</sup> To date, the etiology of

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**Correspondence:** Dr Hong Hua, Department of Oral Medicine and Traditional Chinese Medicine, Peking University School of Stomatology, 22 South Zhongguancun Ave, Haidian District, Beijing 10081, China. Email: honghua68@hotmail.com BMS is poorly understood, and the disorder presents clinical and therapeutic challenges.<sup>2</sup> Although pharmacologic options such as antidepressants and analgesics remain the primary management strategy, many patients continue to experience distress and pain after such treatments.<sup>3</sup> Moreover, the adverse effects of medication may lead to the consideration of nonpharmacologic treatment.

Acupuncture is an alternative medicine involving the insertion and manipulation of fine needles in different parts of the body. It can be used for therapeutic purposes to relieve pain, treat diseases, and promote general health. The term acupuncture is also sometimes used to refer to water needling (acupoint injection) or to applying an electric current to needles in acupuncture points. All of these acupuncture therapies have been widely used to manage chronic pain conditions (eg, headache, fibromyalgia, and head and neck pain), and their efficacy in reducing pain intensity has been demonstrated in the literature.4-6 For BMS, however, there is a lack of evidence regarding the use of acupuncture

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treatment. Therefore, this systematic review aimed to evaluate the evidence regarding the efficacy acupuncture treatment in the management of BMS.

# METHOD AND MATERIALS

#### Search strategies

The following databases were searched for relevant articles: Cochrane Oral Health Group Trials Register (July 2011), Cochrane Central Register of Controlled Trials (issue 7, 2010), MEDLINE (1966 to June 2011), and electronic medical databases from the China National Knowledge Infrastructure (CNKI) (1979 to June 2011). All articles in the CNKI are in Chinese.

Key words used for searching included acupuncture, acupoint, burning mouth syndrome, and glossalgia. A total of 81 trials were found. Abstracts of these studies were screened by two independent reviewers (Z.Y. and N.D.). The full texts of the relevant articles were obtained for further review. Data from letters, abstracts, conference proceedings, case reports, reviews, or noncontrolled studies were excluded.

#### **Selection criteria**

Studies were selected if they met the following criteria: study design—randomized controlled trials and controlled trials; participants—patients with burning mouth syndrome, ie, oral mucosal pain with no dental or medical cause for such symptoms; interventions—acupuncture or acupoint injection evaluated in controlled trials; and primary outcome—relief of pain/burning.

Studies were included only if at least one clinical outcome related to burning sensation (eg, intensity, healthy-related quality of life) was evaluated and recorded. Trials of other acupuncture techniques, such as acupoint injection, were included. Trials using acupuncture points other than needling (eg, millimeter wave therapy) were excluded.

### **Quality assessment**

The quality of each included study was assessed by two independent reviewers based on the criteria of the Jadad Scale.<sup>7,8</sup> When any difference of opinion occurred between the two reviewers, consensus was reached by discussion or consultation of a third party. Only articles that received a Jadad score  $\geq$  1 were included. The maximum score was 5 (2 points for descriptions of randomization, 2 points for descriptions of double blinding, and 1 point for descriptions of withdrawals). Points were awarded as follows:

- Was the study described as randomized? (yes, 1 point; no, 0 points)
- Was the randomization adequate? (yes, 1 point; no, 0 points)
- Was the study described as double blind? (yes, 1 point; no, 0 points)
- Was the blinding adequate? (yes, 1 point; no, 0 points)
- Was there a description of withdrawals and dropouts?
  - (yes, 1 point; no, 0 points)

### **Data extraction**

Two independent reviewers extracted information on participants, intervention, and outcome measurements. The primary outcome was pain relief, and the secondary outcomes were changes in dry mouth, taste, and other somatic symptoms. The primary outcome measurement was needed for inclusion, while secondary outcomes were not necessary.

# RESULTS

#### **Study characteristics**

The two reviewers identified 81 potentially relevant trials. After screening, nine trials consisting of 547 participants met the inclusion criteria and were included in this review (Fig 1). All nine trials were exclusively published in Chinese from 2002 to 2010. No trials published in English were found. The characteristics of the included trials are summarized in Table 1. Six articles reported that the burning sensation had a duration of more than 3 months. Eight trials used acupoint injection as the acupuncture technique, one of which also used electrical needling stimulation. The remaining study (Bai and Yu<sup>9</sup>) used traditional acupuncture in the treatment group.



Fig 1 Article-selection process.

All studies reported at least one clinically related outcome measurement (eg, pain and dry mouth). However, only one study<sup>10</sup> reported use of a visual analog scale to measure pain. The remaining trials reported the number of participants in the categories cured, marked improvement, improvement, or no effect.

### Intervention characteristics

Study objectives varied among the studies. To determine its effectiveness, acupuncture was compared to different pharmacologic controls, including vitamins, traditional Chinese medicines, and acupuncture plus traditional Chinese medicines.

The most commonly used acupoints were LI4, LI11, and SI17. The treatment session ranged from 10 days to 3 weeks. The longest follow-up period was 3 months in two studies (Yong et al<sup>11</sup> and Li and Luo<sup>12</sup>).

De Qi was reported in two trials (Bai and Yu<sup>9</sup> and Huang and Huo<sup>13</sup>) as a phenomenon when the acupuncture point was reached. In traditional Chinese medicine, *de Qi* refers to the sensation felt when an acupuncturist reaches the acupoint at the level of the qi (ie, vital energy) in the body. This sensation may feel like distention, throbbing, or an electrical impulse in the area of the acupoint being addressed. It is generally accepted that the action of a given acupuncture point is assured only when needling is accompanied by de Qi.

### **Quality assessment**

Randomization, blindness, and withdrawals were insufficiently addressed in all nine studies, and a low quality was found for all studies (Jadad score < 3) (Table 1).

All studies divided the patients into two groups and used only a description such as "randomly divided into two groups" without further explanation (Jadad score, 1). Only one article<sup>14</sup> contained the additional explanation "by means of a random number table" (Jadad score, 2). None of the studies mentioned single blinding or double blinding (Jadad score, 0). In all trials, neither the number of lost cases (eg, dropouts, withdrawals, or protocol deviations) nor the reasons for such losses were reported (Jadad score, 0). None of the studies applied intention-to-treat analysis. No articles with "randomly divided into two groups" in their

	Participants			Jadad	Intervention			
Study	n	Sex (% female)	Age (y)	score (0–5)	Treatment course	Treatment	Control	
Qiu <sup>14</sup>	200	60	51.3 ± 10.5 (mean ± SD)	2	10 d	Laser acupuncture	Acupoint injection	
Bai and Yu <sup>9</sup>	70	<b>100</b>	<b>40–65</b>	1	20 d	Electric acupuncture	Oral oryzanol, vitamin B2, and vitamin E	
Huang and Zong <sup>10</sup>	52	84.6	52.3 (mean)	1	20 d × 3	Acupoint injection	Oral oryzanol and vitamin E	
Huang and Huo13	43	79.1	31–75	andre <b>f</b> ilment	20 d	Acupoint injection	Oral oryzanol and vitamin E	
Ma <sup>15</sup>	26	_	40–70	1	20 d	Acupoint injection	Oral oryzanol and vitamin E	
Yong et al <sup>11</sup>	35	85.7	38–60	1	10 d × 5	Acupoint injection + oral oryzanol	Oral oryzanol	
Mo and Liu <sup>16</sup>	38		43–72	1	20 d	Acupoint injection	Oral oryzanol and vitamin E	
Lv and Li <sup>17</sup>	55	83.6	30–75	1	$3  \mathrm{wk}  imes 2$	Acupoint injection	Oral oryzanol and vitamin I	
Li and Luo <sup>12</sup>	28	78.6	43.29 (mean)	1	7 d × 12	Acupoint injection + oral oryzanol, vitamins B and E, and TCM	Oral oryzanol, vitamins B and E, and TCM	

SD, standard deviation; TCM, traditional Chinese medicine.

abstracts reported the concealment measures of randomized allocation, and none reported the calculating basis of sample size.

### **Therapeutic efficacy**

In seven of the trials, acupoint injection therapy was compared with medication as a treatment of BMS. In all seven trials, pain relief in the acupoint injection group was significantly greater than in the control group. The substance used in the acupoint injection was lidocaine accompanied by vitamin B (B1 and B12). The substance and dosage were consistent in all seven studies. Two studies (Yong et al<sup>11</sup> and Li and Luo<sup>12</sup>) applied acupoint injection with oral medication only in the control group. Both studies found greater relief of pain and other symptoms in the acupoint injection group.

Qiu<sup>14</sup> compared acupoint injection with laser acupuncture and found a better response rate in the acupoint injection group. Bai and Yu<sup>9</sup> used traditional acupuncture in the treatment group and oral oryzanol and vitamin B2 in the control group. They found better results in the acupuncture group than in the medication group. None of the nine trials reported the adverse effects related to acupuncture. Oryzanol is widely used in mainland China as an agent for the treatment of nerve imbalance and disorders of menopause. It has been approved in China and Japan for several conditions, including menopausal symptoms, mild anxiety, upset stomach, and high cholesterol. Its mechanism of action may include the antioxidant effect.<sup>18,19</sup>

## DISCUSSION

BMS is a chronic intraoral mucosal pain condition often accompanied by xerostomia and taste disturbances. An incomplete understanding of the etiology and pathophysiology of the disease remains a barrier to effective treatment. There is limited evidence available to guide clinicians in the management of patients with BMS. While clonazepam and cognitive therapy have

D Acupoint		Diagnosis of BMS	Outcomes evaluated
TE17, SI17, ST4	Not reported	Exclusive	Oral symptoms and other somatic symptoms (rating score 1–5)
LI4, RN23, KI3, GV20, EX-HN12, EX-HN13	Yes and the second	Exclusive	Pain relief, dry mouth, and other symptoms
BL20, BL17, BL23, SP10	Not reported	Exclusive	VAS for pain and symptoms
LI4, LI11, SI17 TE17, RN23, ST4	Yes Not reported	Exclusive Exclusive	Burning pain, dry mouth, and sleep quality Pain and other symptoms
ST4, SI17, TE17	Not reported	Exclusive	Pain and taste change
ST4, SI17, TE17	Not reported	Exclusive	Pain and other symptoms
LI4, LI11, SI17	Not reported	Exclusive	Symptoms relief
KI3, SP6, ST36, PC6, TE5, SI17, LI11, LI4	Not reported	Exclusive	Pain and other symptoms

VAS, visual analog scale; BMS, burning mouth syndrome.

been proven effective in some patients, the treatment results are still not satisfactory. One systematic review<sup>20</sup> on BMS examined the use of antidepressants, cognitive behavioral therapy, analgesics, hormone replacement therapy, alpha-lipoic acid, and anticonvulsants. In the nine trials included in that review, none of the interventions examined demonstrated a significant reduction in BMS symptoms. Therefore, there is an urgent need to develop new therapeutic options to decrease the pain and other symptoms of BMS.

Acupuncture has been used as a clinical therapy for more than 5,000 years. It has been reported to promote to pain relief, reduce inflammation, and enhance the immune system. According to the theory of traditional Chinese medicine, when pain occurs, the qi is blocked or out of balance. The pain stops when the qi moves.<sup>21</sup> The term *qi stagnation* refers to a pathologic change characterized by impeded circulation of qi that leads to stagnation of qi movement and functional disorder of the organs, manifested as pain in the affected area. Acupuncture is believed to correct this imbalance and alleviate pain by regulating the blood flow of qi. Therefore, acupuncture is considered especially suited for the treatment of pain conditions, in which psychologic, spiritual, and emotional issues may be involved along with any physical problems. Acupoint injection therapy (ie, water needling) is one acupuncture technique used to inject a medicated solution into an acupoint. It functions by provoking similar physiologic responses as acupuncture but may have more powerful clinical effects since it combines acupuncture and medication.<sup>22</sup>

Many studies have examined acupuncture in pain treatment, including postoperative dental pain,<sup>5,23</sup> fibromyalgia,<sup>24,25</sup> and head and neck pain.<sup>26</sup> However, few clinical trials were found regarding acupuncture for the treatment of BMS. In the present study, the authors searched electronic databases such as MEDLINE without language restrictions. No articles in a language other than Chinese were found. In the Chinese studies of acupuncture as a treatment for BMS, the conclusions were limited by the small number of subjects. Therefore, this systematic review aimed to evaluate the therapeutic

efficacy of acupuncture for the management of BMS. In the studies reviewed here, acupuncture was compared with a variety of control procedures, and various conclusions emerge. The effectiveness of acupuncture/ acupoint injection therapy appeared to be satisfactory in most cases in terms of reducing pain, dry mouth, and other somatic symptoms. This finding agrees with previously published data regarding acupuncture and other pain conditions.<sup>4,27</sup>

The mechanism behind acupuncture in treating BMS remains unknown. One study proposed that acupuncture may reduce the burning sensation in BMS patients by influencing the oral microcirculation.28 BMS patients in the study were treated with acupunctural techniques, and microcirculation was observed in vivo using videocapillaroscopy. It was shown that acupuncture influences oral microcirculation, resulting in a significant variation of the vascular pattern and a significant reduction of the burning sensation after therapy. This reduction of the burning sensation was maintained for 18 months following the acupuncture therapy. Therefore, the study considered acupuncture a valid treatment in the management of BMS.

The present study is the first systematic review to examine the therapeutic efficacy of acupuncture for BMS. In the nine trials included, acupuncture or acupoint injection was found to be effective as a treatment for BMS. The majority of the studies compared true acupuncture with medication therapy (oral oxyzanol and vitamin B2). However, there is still a lack of evidence regarding whether these medications are effective in treating BMS. Although pain and other symptoms were relieved in the 1- to 3-month durations of the trials, long-term outcomes still need to be considered.

There are several limitations to this review. First, the heterogeneity of study results is often considered a limitation in systematic reviews. The heterogeneity of the present review is variable due to the different acupuncture treatments and control designs.

Further, the placebo effect is an important consideration in the management of complex pain conditions such as BMS. Acupuncture may have a specific effect beyond the placebo effect for BMS treatment; however, none of the included studies provided evidence of this by comparing acupuncture with sham controls. In recent years, there have been increasing reports on acupuncture therapy using sham controls in randomized clinical trials. There are several sham acupuncture techniques. One sham intervention, which can be used as a control specifically for acupoint therapy, uses body locations not recognized as true acupoints or meridians for needling (ie, sham needling). Another sham treatment, a control for needle insertion, consists of noninsertive simulated acupuncture at the same acupoints used in directed acupuncture (ie, simulated acupuncture). This technique, in which a toothpick in a needle auide tube is used to mimic needle insertion and withdrawal, has been shown to closely duplicate the needle insertion experience and to be indistinguishable from true acupuncture in acupuncture-naïve patients.29-31

Finally, the methodologic quality of the studies, as assessed by the modified Jadad score for clinical trials, was disappointing. Many studies lacked adequate blinding strategies. Therefore, high-quality studies with additional design features (eg, blinding, sham control, and standardization of the interaction between the acupuncturists) are required to verify the efficacy of acupuncture for the management of BMS.

# CONCLUSION

Studies in China supported the effectiveness of acupuncture for the management of BMS. However, high-quality randomized controlled trials are lacking. In light of the positive outcomes reported, the efficacy of acupuncture therapy in the treatment of BMS warrants further research.

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