

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases**References**

Bessho K, Okubo Y, Hori S, et al. Effectiveness of Kampo medicine (sai-boku-to) in treatment of patients with glossodynia. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology* 1998; 86: 682-6. CENTRAL ID: CN-00158400, Pubmed ID: 9868725

Yamada T, Bessho K, Murakami K, et al. Clinical evaluation of sai-boku-to (Kampo medicine) for glossodynia. *Shika Yakubutsu Ryoho (Oral Therapeutics and Pharmacology)* 1998; 17: 18-22 (in Japanese with English abstract) [MOL](#), [MOL-Lib](#)

Yamada T, Bessho K. Clinical evaluation of sai-boku-to (Kampo medicine) for glossodynia. *Kampo to Saishin-chiryō (Kampo & the Newest Therapy)* 1999; 8: 261-5. Ichushi Web ID: 2000085045

1. Objectives

To evaluate the efficacy of saibokuto (柴朴湯) compared with tranquilizer plus vitamin B complex combination therapy for patients with glossodynia.

2. Design

Randomized controlled trial (RCT).

3. Setting

Department of Oral and Maxillofacial Surgery Kyoto University Hospital, Japan.

4. Participants

Two hundred patients with glossodynia.

5. Intervention

Arm 1: treatment with TSUMURA Saibokuto (柴朴湯) Extract Granules, 2.5g, t.i.d. for 3 months. (n=100)
Arm 2: treatment with diazepam, 2mg, t.i.d. plus vitamin B complex formulation, 1 tablets, t.i.d. for 3 months. (n=100)

6. Main outcome measures

Each of the subjective symptoms (pain, burning sensation, and unpleasant feeling) was evaluated on a 10-point scale. 'Excellent response' was defined as disappearance of all symptoms, 'good response' as improvement of pain, and 'no response' as no improvement of pain.

7. Main results

In arm 1, the percentage of excellent and good responses was 70% at 1 month, 85% at 2 months, and 92% at 3 months after the start of treatment. These values in arm 2 were 74%, 71%, and 69%, respectively ($P<0.05$). Pain relief was experienced in a significantly higher percentage in arm 1 than in arm 2 at 3 months ($P<0.01$).

8. Conclusions

It is suggested that saibokuto (in particular, the three-month treatment) is more effective against glossodynia than the diazepam plus vitamin B complex formulation.

9. From Kampo medicine perspective

The discussion contains some speculations.

10. Safety assessment in the article

Mild anorexia and diarrhea were reported, respectively, in 3 and 1 patient receiving saibokuto, and severe sleepiness was reported in 33 patients receiving diazepam.

11. Abstractor's comments

This study suggests that saibokuto monotherapy (for 3 months) is more effective against glossodynia than the combination therapy (tranquilizer plus vitamin B complex). Also, saibokuto treatment is safe, as indicated by the low frequency of adverse effects and the possibility of long-term treatment. Although the sample size of the study described in the two papers by Yamada et al (1998, 1999) was about half that in the present study, the results were very similar.

12. Abstractor and date

Okabe T, 17 September 2008, 1 June 2010, 31 December 2013.