11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

References


Yamada T, Bessho K. Clinical evaluation of sai-boku-to (Kampo medicine) for glossodynia. Kampo to Saishin-chiryo (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. **Abstracter’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. **Abstracter and date**