

5. Psychiatric/Behavioral Disorders

Reference

Ishida H, Otake T, Kurihara H, *et al.* Clinical study on augmentative effect of saiboku-to for anxiolytic and antidepressant action of diazepam. *Pain Clinic*, 1999; 20: 395-9 (in Japanese).

1. Objectives

To evaluate the efficacy of saibokuto (柴朴湯) as a potentiator of the anxiolytic and antidepressant effects of diazepam.

2. Design

Randomized controlled trial (RCT).

3. Setting

A single clinic (pain clinic), Japan.

4. Participants

Fifteen patients with chronic anxiety or depression were included for analysis.

5. Intervention

Arm 1: oral administration of 7.5 g/day of saibokuto (柴朴湯) extract granules (manufacturer, not specified; frequency, not specified) for 2 weeks followed by 6 mg/day of diazepam for 2 weeks. (n=7)

Arm 2: oral administration of 6 mg/day of diazepam for 2 weeks. (n=8)

6. Main outcome measures

Hamilton Rating Scale (HS) score, diazepam and desmethyldiazepam blood levels, motor nerve conduction velocity (MCV)

7. Main results

Mean HS scores were 11.0, 7.4, and 4.1 before and after saibokuto and after diazepam, respectively, in Arm 1, while 8.9 and 5.5, respectively, before and after diazepam in Arm 2. Significant improvement in HS score was observed after diazepam in both arms. No between-arm difference was seen in diazepam and desmethyldiazepam blood levels or MCV.

8. Conclusions

Administration of saibokuto followed by diazepam, compared with diazepam monotherapy, has at least an equal anxiolytic and antidepressant effect.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

None.

11. Abstractor's comments

The study comparing diazepam monotherapy with saibokuto and subsequent diazepam for anxiolytic and antidepressant treatment in patients with anxiety neurosis in a randomized controlled trial provides a high quality of evidence. The statement concluding that administration of saibokuto was likely to be associated with clinical improvement of symptoms was in the Discussion, although not in the Results. Despite the small sample size, it is likely that the effect of diazepam was enhanced by prior saibokuto treatment, so studies with larger sample size are needed. A trend towards clinical improvement of symptoms in the saibokuto arm was presented as a conclusion in the Discussion, but the measures of clinical symptoms are not mentioned. Providing details of these measures would improve the quality of this study.

12. Abstractor and date

Goto H, 15 June 2007, 1 April 2008, 1 June 2010.