

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

Hasebe K, Machida M, Yada M, et al. Clinical application of Keishi-ka-syakuyaku-to for abdominal symptoms caused by the α -glucosidase inhibitor acarbose. *Kiso to Rinsho (The Clinical Report)* 1997; 31: 3179-86 (in Japanese with English abstract). Ichushi Web ID: 1998043002 [MOL](#), [MOL-Lib](#)

1. Objectives

To evaluate the efficacy and safety of keishikashakuyakuto (桂枝加芍薬湯) for the treatment of acarbose-induced symptoms.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

Single institution (Showa General Hospital), Japan.

4. Participants

Twenty patients with non-insulin-dependent diabetes mellitus (NIDDM) and poor glycemic control in spite of diet and exercise.

5. Intervention

Arm 1: treatment with acarbose (50 mg t.i.d. right before meals) plus TSUMURA Keishikashakuyakuto (桂枝加芍薬湯) Extract Granules (2.5 g t.i.d. before meals) (n=10).

Arm 2: treatment with acarbose alone (n=10).

The treatment duration was 4 weeks.

6. Main outcome measures

Subjective symptoms (abdominal distension, flatus, flatulence, abdominal pain, borborygmus, diarrhea, loose stool, and constipation) were scored on a 4-point scale at baseline, and after 2 and 4 weeks of treatment.

Fasting blood glucose and glycosylated hemoglobin (HbA1c) levels were measured at baseline and after 4 weeks.

7. Main results

Subjective symptoms worsened in both arms at 2 weeks, but diarrhea and abdominal pain disappeared at 4 weeks only in arm 1. The total subjective symptom score decreased significantly both at 2 and 4 weeks in arm 2, while it decreased at 2 weeks but returned to baseline level at 4 weeks in arm 1. No significant change in fasting blood glucose occurred in either arm, whereas HbA1c level was significantly improved after 4 weeks of the combination therapy.

8. Conclusions

Keishikashakuyakuto is effective for relieving gastrointestinal symptoms (adverse drug reactions to acarbose, an α -glucosidase inhibitor [α -GI]). The combination can reduce HbA1c level.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

There was no significant worsening of subjective symptoms in the combination group.

11. Abstractor's comments

Abdominal symptoms frequently occur as so-called adverse drug reactions to acarbose, an α -GI used for mild diabetes mellitus, and may lead to discontinuation of the drug. The reduction or elimination of these symptoms by keishikashakuyakuto helps patients continue acarbose treatment. For mild diabetes mellitus, however, other drugs have been developed and more treatment options are available now. Therefore, it is controversial to add an oral drug, even a Kampo medicine, just for the purpose of continuing acarbose treatment. Also, blood glucose or HbA1c level was not significantly reduced by acarbose in this study, indicating that there might have been an inhomogeneity of the study population. These results suggest that acarbose plus keishikashakuyakuto improves glucose tolerance and that oral administration of keishikashakuyakuto in selected patients may provide a way to continue the acarbose treatment. Further studies on this combination therapy are anticipated.

12. Abstractor and date

Namiki T, 29 December 2008, 1 June 2010.