

7. Eye Diseases

References

Nagaki Y, Hayasaka S, Hayasaka Y, et al. Effects of goshajinkigan on corneal sensitivity, superficial punctate keratopathy and tear secretion in patients with insulin-dependent diabetes mellitus. *The American Journal of Chinese Medicine* 2003; 31: 103-9. CENTRAL ID: CN-00437062, Pubmed ID: 12723759

Nagaki Y. Effects of goshajinkigan on diabetic keratopathy*. *Kampo Igaku (Kampo Medicine)* 2004; 28: 63-5 (in Japanese).

1. Objectives

To evaluate the efficacy of goshajinkigan (牛車腎気丸) for corneal sensitivity, superficial keratitis, and tear secretion in patients with insulin-dependent (type 1) diabetes mellitus.

2. Design

Double-blinded randomized controlled trial (DB-RCT).

3. Setting

Toyama Medical and Pharmaceutical University Hospital (now Toyama University Hospital), Department of Ophthalmology, Japan.

4. Participants

Fifty patients with insulin-dependent diabetes mellitus complicated with keratopathy. Participants met the following selection criteria: (1) 5 years or longer duration of insulin dependence; (2) simple or preproliferative diabetic retinopathy; (3) diffuse superficial keratitis revealed by fluorescein staining; (4) no history of eye disease other than diabetic retinopathy; and (5) no treatment with eye drops in the past 3 months.

5. Intervention

Arm 1: treatment with TSUMURA Goshajinkigan (牛車腎気丸) Extract Granules 2.5 g t.i.d. (30 minutes before meals) for 3 months in 25 patients (age 25.5±6.9 years; male:female = 10:15; 14 with simple retinopathy and 11 with proliferative retinopathy; disease duration 11.6±5.7; group A).

Arm 2: treatment with placebo granules (lactose granules not containing extract powder) 2.0 g t.i.d. (30 minutes before meals) for 3 months in 25 patients (age 26.6±5.2 years; male:female = 13:12; 14 with simple retinopathy and 11 with proliferative retinopathy; disease duration 11.6±5.7; group B).

Arm 3: treatment with goshajinkigan (牛車腎気丸) for 3 months in 25 healthy volunteers (age 26.2±5.4 years; male:female = 11:14; group C).

6. Main outcome measures

Corneal sensitivity, fluorescein staining score, and Schirmer score were evaluated before and after the treatment.

7. Main results

Corneal sensitivity significantly improved from the pre-treatment value of 2.47±1.1 to the post-treatment value of 2.03±0.63 in group A ($P<0.05$) but not in group B (2.36±1.35 and 2.33±1.02, respectively). Schirmer score markedly improved from the pre-treatment value of 9.3±3.5 to the post-treatment value of 11.0±3.3 in group A ($P<0.01$) but not in group B (9.0±3.8 and 9.0±4.0, respectively). Fluorescein staining score markedly improved from the pre-treatment value of 1.32±0.56 to the post-treatment value of 0.64±0.49 in group A ($P<0.01$) but not in group B (1.40±0.64 and 1.36±0.68, respectively). Corneal sensitivity, Schirmer score, and fluorescein staining score all remained within their normal ranges in group C.

8. Conclusions

Goshajinkigan improves reduced corneal sensitivity, increases tear secretion, and markedly repairs damage to the corneal surface, thereby improving keratopathy without affecting the progression of diabetes mellitus.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No adverse drug reactions were observed.

11. Abstractor's comments

This study was a double-blind RCT involving 50 diabetic patients (groups A and B). It is a well-designed clinical trial in which both prescribing physician and patients were blinded. If more details, such as data on withdrawals, had been described, intention-to-treat (ITT) analysis data and more reliable results could have been obtained. Further studies are expected to determine effects of goshajinkigan on ocular complications of type 2 diabetes mellitus as a lifestyle-related disease.

12. Abstractor and date

Tsuruoka K, 15 June 2007, 1 April 2008, 1 June 2010, 31 December 2013.