Evidence Reports of Kampo Treatment

Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

7. Eye Diseases

Reference

Ikeda N, Hayasaka S, Nagaki Y, et al. Effects of traditional Sino-Japanese herbal medicines on aqueous flare elevation after small-incision cataract surgery. *Journal of Ocular Pharmacology and Therapeutics* 2001; 17: 59-65. CENTRAL ID: CN-00347524, Pubmed ID: 11322638

1. Objectives

To evaluate the efficacy of Kampo medicines for aqueous flare elevation after small-incision cataract surgery.

2. Design

Randomized controlled trial (RCT).

3. Setting

Toyama Medical and Pharmaceutical University Hospital (now Toyama University Hospital) and an affiliated hospital, Japan.

4. Participants

Fifty-four patients undergoing surgery for age-related cataract. Patients with complications (such as diabetes mellitus and autoimmune disease), a history of uveitis, or use of anti-inflammatory drugs were excluded.

5. Intervention

- Arm 1: no medication in 20 patients (8 males and 12 females; 9 right eyes and 11 left eyes; mean age, 73.1 years [48-85 years]) as a control group.
- Arm 2: treatment with TSUMURA Orengedokuto (黄連解毒湯) Extract Granules 7.5 g/day for 3 days before surgery, on the day of surgery, and for 7 days after surgery in 14 patients (5 males and 9 females; 8 right eyes and 6 left eyes; mean age, 74.5 years [56-90 years]).
- Arm 3: treatment with TSUMURA Kakkonto (葛根湯) Extract Granules7.5 g/day on the same schedule as arm 2 in 10 patients (3 males and 7 females; 6 right eyes and 4 left eyes; mean age, 75.5 years [68-83 years]).
- Arm 4: treatment with TSUMURA Saireito (柴苓湯) Extract Granules 9.0 g/day on the same schedule as arm 2 in 10 patients (5 males and 5 females; 4 right eyes and 6 left eyes; mean age, 73.8 years [61-84 years]).

Cataract surgery in all patients was performed by a single surgeon according to a standard small-incision procedure.

6. Main outcome measures

Aqueous flare intensity (in photon counts/msec) was measured preoperatively and on postoperative days 1, 3, 5, and 7.

7. Main results

Preoperatively, no differences were observed in aqueous flare intensity among the groups. Aqueous flare intensity on postoperative days 1, 3, and 5 was significantly lower in the orengedokuto group (P<0.05) and kakkonto group (P<0.01) than in the control group. There was no difference between the saireito and control groups.

8. Conclusions

Orengedokuto and kakkonto reduce aqueous flare elevation after small-incision cataract surgery.

9. From Kampo medicine perspective

Evaluation of *sho* and selection of Kampo formulations for each patient were conducted at the Kampo medicine clinic (now Department of Japanese Oriental Medicine) in the above-mentioned university hospital.

10. Safety assessment in the article

No adverse drug reactions were observed.

11. Abstractor's comments

Aqueous flare intensity was used in this RCT as a measure of intraocular inflammation after cataract surgery. Since aqueous flare is a surrogate outcome, results from clinical trials examining other outcomes such as reduction of treatment duration and dosage of commonly used postoperative medication are anticipated. See the article "Ikeda N, Hayasaka S, Nagaki Y, et al. Effects of Kakkon-to and Sairei-to on aqueous flare elevation after complicated cataract surgery. *The American Journal of Chinese Medicine* 2002; 30: 347-53", as a follow-up of the present study.

12. Abstractor and date

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