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 kakkon-to and sairei-to on aqueous flare elevation after complicated cataract surgery. *The American Journal of Chinese Medicine* 2002; 30: 347-53. CENTRAL ID: CN-00434525, Pubmed ID: 12230023

# 1. Objectives

To evaluate the efficacy of Kampo medicines for aqueous flare elevation after complicated cataract surgery.

## 2. Design

Randomized controlled trial (RCT).

## 3. Setting

One hospital (one department of ophthalmology), Japan.

## 4. Participants

Twenty-seven patients with bilateral cataracts (54 eyes were eligible) associated with idiopathic or sarcoid uveitis. Of these patients, 5 were excluded from analysis.

## 5. Intervention

No Kampo formulation was administered in right eye surgeries. In left eye surgeries, one of the following Kampo formulations was administered for 3 days before surgery, on the day of surgery, and for 7 days after surgery.

Arm 1: treatment with TSUMURA Kakkonto (葛根湯) Extract Granules 2.5 g t.i.d. in 12 patients (mean age, 64.2 years [48-75 years]; 6 males and 6 females; 9 with idiopathic uveitis and 3 with sarcoid uveitis).

Arm 2: treatment with TSUMURA Saireito (柴苓湯) Extract Granules 3.0 g t.i.d. in 10 patients (mean age, 73.8 years [61-84 years]; 7 males and 8 females; 12 with idiopathic uveitis and 3 with sarcoid uveitis).

Cataract surgery in all patients was performed by a single surgeon following a standard 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, aqueous flare intensity was not different between the two groups. For right eyes, flare intensity was 99.1 in the kakkonto group and 89.6 in the saireito group on postoperative day 1, and then gradually decreased in both groups. For left eyes, compared with the untreated right eyes, aqueous flare intensity was significantly decreased in the kakkonto group on postoperative days 1, 3, and 5 (P<0.001 for each). In contrast, there was no difference between left and right eyes in the saireito group.

## 8. Conclusions

Kakkonto inhibits the elevation in aqueous flare intensity after complicated 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

This study was conducted as a follow-up to the preceding study "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". Participants in the present study were different from those in the preceding study, and patients with both cataracts and uveitis were examined. Also, kakkonto, which had been more effective than orengedokuto in the preceding study, was used as a test Kampo drug. These studies were conducted by the same investigators and the blinding was not described in either article; suggesting that these might have been single-blind studies.

## **12.** Abstractor and date

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