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

12. Skin Diseases

Reference

Kusumoto M, Fujimura Y, Yamada H, et al. Evaluation of the effectiveness of various drugs for relieving itching due to eczema carried out by personnel in inpatient pharmacy practice: assessment based on "itching" score - *. *Iyaku Journal (Medicine and Drug Journal)* 1993; 29: 973–6 (in Japanese).

1. Objectives

To compare the effect of unseiin (温清飲), antiallergic drugs, and antihistamines on itching due to eczema and other skin disorders.

2. Design

Randomized controlled trial (RCT).

3. Setting

One dermatology ward at a general hospital, Japan.

4. Participants

One hundred inpatients with eczema-induced itching and other skin disorders (60 males and 40 females): atopic dermatitis (n=42), asteatotic eczema (n=12), contact dermatitis (n=7), psoriasis (n=7), seborrheic dermatitis (n=6), and others (n=26). Age (in years) was 0-5 (n=2), 6-15 (n=23), and 16 or older (n=75).

5. Intervention

Arm 1: Kampo monotherapy: administration of TSUMURA Unseiin (温清飲) Extract Granules 7.5 g/day for 2 weeks (n=25).

- Arm 2: antiallergic drug monotherapy: administration of Celtect (oxatomide) 2 tablets/day for 2 weeks (n=23).
- Arm 3: Kampo medicine + antiallergic drug: administration of TSUMURA Unseiin (温清飲) Extract Granules 7.5 g/day + Celtect 2 tablets/day for 2 weeks (n=27).

Arm 4: antihistamine: administration of Tavegyl (clemastine) 2 tablets/day for 2 weeks (n=25).

6. Main outcome measures

The degree of itching was scored on a 5-point scale (0: no symptoms, 1: slight itching, 2: mild itching, 3: moderate itching, 4: intense itching). Patients themselves recorded the score every 1 hour. Daily total scores were calculated for days at the beginning, middle, and end of hospitalization.

7. Main results

The mean total scores for arms 1, 2, 3, and 4, respectively were 15.42, 15.69, 20.33, and 21.84 (first day), 14.70, 12.62, 14.88, and 17.12 (middle of hospitalization), 7.84, 8.06, 7.07, and 9.68 (last day). In all arms, significant differences were observed between the first and last days. The mean changes in scores from the first to last day were 7.58, 7.38, 13.59, and 12.16 in arms 1, 2, 3, and 4, respectively, and there were significant differences between arms 1 and 3, 1 and 4, 2 and 3, and 2 and 4 and no significant between-arm differences in sex, type of disease, and age.

8. Conclusions

All treatments significantly decrease itching. The effects in arms 1 and 2 as well as arms 3 and 4 are similar. The antipruritic effect is greater in arms 1 and 2 than in arms 3 and 4.

9. From Kampo medicine perspective

The authors noted that assessment of the efficacy of unseiin as well as other Kampo medicines for itching based on *sho* (証, pattern) is challenging.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

In this RCT, degree of itching was considered an outcome measure. Since strong itching (scored 3 or 4) is associated with other symptoms such as insomnia, an assessment of the effect of antihistamine or antiallergic drugs on sleep would be informative. A more extensive study is expected.

12. Abstractor and date

Tsuruoka K, 13 April 2008, 1 June 2010, 31 December 2013.