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

9. Cardiovascular Diseases

References

Abe Y. The efficacy of goshajinkigan against lymphedema^{*}. *Kampo Igaku (Kampo Medicine)* 2002;25:284-7 (in Japanese). Ichushi Web ID: 2002140795 Abe Y, Kosugi I, Kasashima F, et al. Lymphedema and Kampo^{*}. *Progress in Medicine* 2003; 23: 1538-9 (in Japanese). MOL, MOL-Lib

1. Objectives

To evaluate the efficacy and safety of goshajinkigan (牛車腎気丸) in the treatment of lymphedema.

2. Design

Design Randamized controlled trial (RCT).

3. Setting

One hospital (department of cardiovascular surgery), Japan.

4. Participants

A total of 80 patients with lymphedema of the upper limbs (n=40) and lower limbs (n=40).

5. Intervention

Arm 1: oral administration of TSUMURA Goshajinkigan (牛車腎気丸) Extract Granules (TJ-107) 2.5g t.i.d for 1 month in combination with compression therapy (n=40). Arm 2: compression therapy without administration for 1 month (n=40).

6. Main outcome measures

Percentage reduction in edema: reduction in limb circumference assessed between the first visit (baseline) and after 1-month treatment was divided by baseline limb circumference, and expressed in percentage.

7. Main results

For lymphedema of the upper limbs, there was significant percentage reduction in arm 1 (15 \pm 3.4%) compared with arm 2 (5.7 \pm 1.2%; *P*<0.05). For lymphedema of the lower limbs, the percentage reduction was also significant in arm 1 (17.5 \pm 2.8% *vs* 6.7 \pm 0.8% in Arm 2; *P*<0.05).

8. Conclusions

Edema is significantly reduced in both patients with lymphedema of the upper limbs and those with lymphedema of the lower limbs by TSUMURA Goshajinkigan Extract Granules (TJ-107).

9. From Kampo medicine perspective None.

10. Safety assessment in the article None.

11. Abstractor's comments

The indications for goshajinkigan are chronic nephritis, nephritic syndrome, low back pain, edema in the lower extremity, and oliguria. This RCT assessed the efficacy of goshajinkigan for the treatment of lymphedema secondary to surgical procedures. Secondary lymphedema is generally intractable in many cases despite combined treatments including lymph drainage massage, compression skin care, exercise therapy under compression, and administration of anticoagulants. It is very meaningful that goshajinkigan was shown to be efficacious. The problem is that this paper is published in a business periodical without peer review, and information on patients' background and so on is therefore insufficient. Also, since the efficacy of goshajinkigan plus compression was assessed, the effect of goshajinkigan alone will need to be evaluated by comparison with placebo and positive control drugs in the future.

12. Abstractor and date

Namiki T, 15 June 2007, 1 April 2008, 1 June 2010, 31 December 2013.