

9. Cardiovascular Diseases

Reference

Uchida N. A Randomized controlled trial of the Chinese herbal medicine keisi-bukuryo-gan (gui-zhi-fu-ling-wan) in the treatment of deep vein thrombosis. *Jomyakugaku (The Japanese Journal of Phlebology)* 2009; 20: 1-6 (in Japanese with English abstract). Ichushi Web ID: 2009139345

1. Objectives

To evaluate the effect of keishibukuryogan (桂枝茯苓丸) on swelling in patients with deep vein thrombosis (DVT) of the lower limb.

2. Design

Randomized controlled trial (RCT).

3. Setting

Department of Surgery, Mito Red Cross Hospital, Japan.

4. Participants

Twelve patients diagnosed with DVT of the lower limb by ultrasonography at the above-mentioned institution between January 2003 and December 2007.

5. Intervention

Arm 1: heparin (10,000 units/day) and urokinase (240,000 units/day), followed by oral warfarin plus TSUMURA Keishibukuryogan (桂枝茯苓丸) 2.5 g t.i.d. before meals for 6 months (n=6).

Arm 2: heparin (10,000 units/day) and urokinase (240,000 units/day), followed by oral warfarin (n=6). There were no differences in age, gender, and status of the affected limbs between the two arms.

6. Main outcome measures

Difference in the lower-leg circumference between the healthy and affected limb over the 6-month period of keishibukuryogan administration.

7. Main results

The difference in the lower-leg circumference decreased significantly in both arms ($P < 0.05$), while the rate of improvement ($[(\text{pre-treatment circumference difference} - \text{post-treatment circumference difference}) / \text{pre-treatment circumference difference}] \times 100\%$) was significantly higher in arm 1 ($66.1 \pm 20.5\%$) than in arm 2 ($34.0 \pm 13.7\%$; $P = 0.05$).

8. Conclusions

The administration of keishibukuryogan combined with warfarin following heparin and urokinase appears to be effective for reducing swelling associated with DVT of the lower limb.

9. From Kampo medicine perspective

Keishibukuryogan is a therapeutic agent for *oketsu* (瘀血, static blood) and appears to be effective for the treatment of DVT of the lower limb stemming from pathological conditions such as changes in blood coagulability, reduced blood fluidity, and microcirculatory disturbance. Patient selection and outcome from the perspective of Kampo medicine, such as the *bensho* (弁証, Kampo diagnosis) of *qi-ketsu-sui* (気血水, qi, blood, and water) or *gozou roppu* (五臟六腑, five viscera and six bowels) (気血水、五臟六腑弁証), are not mentioned in this paper.

10. Safety assessment in the article

Adverse reactions to keishibukuryogan were not reported.

11. Abstractor's comments

This study evaluated the effects of keishibukuryogan, a *kuoketsuzai* (驅才血劑, blood stasis-expelling formula), on swelling associated with DVT of the lower limb. This swelling may be caused by venous system dysfunction, impaired circulation through lymph vessels, or inflammation. While the site of action of keishibukuryogan is unknown, the paper suggests that *oketsu* may be involved in the pathogenesis of the swelling. The findings in this paper have introduced a new treatment for refractory DVT of the lower limb that appears to be valuable for clinical practitioners. I hope that, in the future, the mechanism (or mechanisms) of action of keishibukuryogan will be elucidated by the accumulation of cases and investigational approaches from different directions.

12. Abstractor and date

Ushiroyama T, 6 January 2010, 31 December 2013.