18. Symptoms and Signs

Reference

Jang IS, Ko CN, Lee I, et al. Effect of Cardiotonic Pills[®] (心適丸) on chest pain and discomfort: A multi-center double-blind randomized controlled trial. *Daehan-Hanui-Hakhoeji* (*Journal of Korean Oriental Medicine*) 2005; 26(2): 95–104 (in Korean with English abstract).

1. Objectives

To evaluate the effect of Cardiotonic Pills® (心適丸) on chest pain and discomfort.

2. Design

Double-blinded randomized controlled trial (DB-RCT).

3. Setting

Four Oriental hospitals (Kangnma Kyugnhee, Usuk Jeonju, Wonkwang Iksan, and Bundangcha Oriental Hospital), Republic of Korea.

4. Participants

Males and females (age, 20–70 years) presenting as outpatients between August 2003 and July 2004 with chest pain and discomfort more than once during a 2-week observation period (n=67).

5. Intervention

Arm 1: Cardiotonic Pills® (心適丸) (Sam Chun Dang Pharm. Co.,Ltd, Contents: Salviae Miltiorrhizae Radix, Notoginseng Radix, Borneolum Syntheticum) (n=33).

Arm 2: Placebo control (Caramel, Polyethylene Glycol 6000, Polyethylene Glycol 400, Bornel) (n=34).

Of 67 subjects, 17 subjects dropped out during the study (8 in Arm 1, 9 in Arm 2).

Course of treatment: 3 times per day, 10 pills per treatment for 8 weeks (56 days).

6. Main Outcome Measures

Score on global assessment scale (severity of illness, global improvement).

7. Main Results

During the observation period, 14 out of 81 participants were excluded. During the clinical trial, 8 patients in Arm 1 and 9 patients in Arm 2 withdrew. There was no between-group difference in age (43.3±7.5 in Arm 1 and 46.0±9.6 in Arm 2). Totally, 50 patients (25 in each arm) were included for analysis. The 8-week treatment significantly reduced the severity of illness in Arm 1 (14/25=0.56) compared to Arm 2 (7/25=0.28). Overall improvement, and improvements in total symptom score and frequency of symptoms were greater in Arm 1 than Arm 2, but the between-group differences were without significance.

8. Conclusions

Cardiotonic Pills provide significant relief of chest pain and discomfort. Therefore, this drug can be used to treat chest pain and discomfort related to cardiac diseases, or of unknown cause.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This study evaluated the effect of Cardiotonic Pills on chest pain and discomfort. The global assessment score showed significant improvement in those treated with Cardiotonic Pills compared with those treated with placebo. As there are few randomized, controlled trials, this study is of great importance. However, the small number of subjects and insufficiently described mechanism of action are deficiencies of this study.

11. Abstractor and date

Jang GT, 31 August 2010.