4. Metabolism and Endocrine Diseases

Reference

1. Objectives
To compare the efficacy of Chunghyul-dan (淸血丹) with that of atorvastatin (Lipitor®) in lowering lipid levels.

2. Design
Randomized controlled trial (RCT).

3. Setting
One Oriental hospital and one Western hospital (2 hospitals) (Kyounghee University Medical Center), Republic of Korea.

4. Participants
Sixty-two hyperlipidemia patients with total cholesterol level of over 240 mg/dl or LDL-cholesterol level of over 160 mg/dl.

5. Intervention
Arm 1: Low-dose Chunghyul-dan (淸血丹) treatment group (n=33). Treatment with chunghyul-dan for 8 weeks (2 capsules per day).
Arm 2: High-dose Chunghyul-dan (淸血丹) treatment group (n=16). Treatment with Chunghyul-dan for 8 weeks (4 capsules per day).
Arm 3: Atorvastatin treatment group (n=13). Treatment with atorvastatin (10 mg per day).

6. Main outcome measures
1) Total cholesterol, low density lipoprotein (LDL)-cholesterol, high-density lipoprotein (HDL)-cholesterol, triglyceride, total lipid, and phospholipid levels.
2) Aspartate aminotransferase (AST), alanine aminotransferase (ALT), blood urea nitrogen (BUN), and creatinine levels.

7. Main results
1) Chunghyul-dan (both doses) and atorvastatin significantly decreased total cholesterol, LDL-cholesterol, total lipid, and phospholipid levels.
2) There were no significant between or among-group differences in total cholesterol, LDL-cholesterol, HDL-cholesterol, triglyceride, total lipid, and phospholipid at the end of the trial.
3) Low and high doses (2 and 4 capsules, respectively) of Chunghyul-dan produced similar decreases in outcome measures.

8. Conclusions
Treatment with Chunghyul-dan and atorvastatin can decrease levels of blood lipids. No adverse events or side effects were observed, suggesting the safety of Chunghyul-dan as treatment for hyperlipidemia.

9. Safety assessment in the article
Chunghyul-dan and atorvastatin were not associated with hepatotoxicity or nephrotoxicity. There were no significant between-group differences between the two groups in biochemical parameters including AST, ALT, BUN and creatinine.

10. Abstractor’s comments
In this study, the therapeutic effect of Chunghyul-dan on serum lipids was comparable to that of the conventional hyperlipidemia drug, atorvastatin. Although this clinical trial used a Western drug control instead of a placebo control and involved comparing patients who were not randomized, it is suggested that the lipid lowering effect and safety of Chunghyul-dan was demonstrated and can be regarded as a clinical basis for using the drug to treat hyperlipidemia.

11. Abstractor