

CHAPTER 6

CONCLUSION

This study was a randomized, double-blind, controlled clinical trial which was designed to compare the hemodynamic and clinical effects of Enalapril added as an additional drug in the treatment of children with congestive heart failure in conjunction with conventional therapy.

84 cases were enrolled with 42 in each group. After stratified by cause of CHF (CHF with Congenital Heart Disease or CHF with Impaired Cardiac Function), all eligible patients received conventional therapy at least 48 hours before trial started. Then Enalapril group received enalapril plus conventional therapy, controlled group received placebo plus conventional therapy.

At the end point of 14 days treatment, 55% patients in Enalapril group, the left ventricular contractility index moved up to the normal range, compare to controlled group only 23% patient's contractility back to normal range ($p < 0,05$). Both group show a significant increase of VCFc, Enalapril group show an additional significant increase of VCFc (0.1circ/s) over the controlled group by comparing absolute mean change before and after treatment. Clinically, both group after 14 days treatment significantly reduced heart rate, respiratory rate and liver size, which represented the improvement of cardiac congestion. Comparing the absolute mean change before and after treatment between two groups, our results show enalapril group achieved further improvement significantly. Body weight and cardiac size (cardiathorecic ratio) changed significant within group, but no significant difference between two groups.

This indicate that in short term, enalapril may not produce more benefit in changing cardiac chamber size or gaining more body weight.

No severe side effects have been found in this study. There is a trend of more serum creatinine and urea decreasing by Enalapril treatment. Serum sodium and potassium tend to be slightly increased after treatment within the group. No significant difference between two groups.

Patients were well tolerated to the dose of Enalapril 0.25mg/kg/day, and maintain a stable blood pressure during the treatment period. No one withdraw from the study because of the severe side effects.

Overall, this study show Enalapril adding as an additional drug into conventional therapy can provide additional hemodynamic and clinical benefits compare with conventional therapy alone.

LVWS-VCFc contractility is sensitive to represent the change of cardiac systolic function.

This is a first randomized, controlled study of enalapril in treating pediatric patients. Due the limitation of experience and the limitation of short period observation, some questions remain to be answered. The further long term study and economic analysis is necessary to demonstrate the long term efficacy, safety and economic impact.