ORIGINAL ARTICLES

Effects of Kanlijian (坎离煎) on Exercise Tolerance, Quality of Life, and Frequency of Heart Failure Aggravation in Patients with Chronic Heart Failure

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ABSTRACT  Objective: To observe the effects of conventional therapy combined with Kanlijian ( 坎离煎, KLJ) on exercise tolerance, quality of life and frequency of heart failure aggravation in patients with chronic heart failure(CHF). Methods: Sixty CHF patients differentiated as suffering from the syndrome of Xin-Shen Yang deficiency were included in the study and randomly assigned at the ratio of 2 : 1 into the KLJ group (n = 39) and the control group (n = 21). All the patients were treated with conventional therapy of Western medicine, but to those in the KLJ group, KLJ was medicated additionally one dose daily with 24 wks as one therapeutic course. The efficacy on TCM syndrome and changes of scores on TCM syndrome were observed after treatment. The indexes, including 6-minute walking distance (6MWD), quality of life (QOL, accessed by LHFQ scoring), NYHA grade, hemodynamic indexes and reducing/withdrawal rate of diuretic and digoxin before and after treatment were recorded and compared. Also the frequency of re-admission due to aggravation of heart failure in one year’s time were observed. Results: (1) The efficacy on TCM syndrome, improvement on scores of TCM syndrome, therapeutic effects on 6MWD, QOL, and NYHA grade in the KLJ group were superior to those in the control group. (2) Hemodynamic indexes after treatment, left ventricular fractional shortening (LVFS) and E peak/A peak (E/A), between the two groups had no significant difference, while left ventricular ejection fraction (LVEF) was increased significantly in the KLJ group, but with no obvious change in the control group. (3) The reducing/withdrawal rate of diuretic and digoxin in the KLJ group was significantly higher than that in the control group. (4) The 1-year frequency of re-admission significantly decreased in the KLJ group. Conclusion: The adjuvant treatment of KLJ on the basis of Western conventional therapy can significantly improve CHF patients’ exercise tolerance, quality of life and cardiac function, reduce the dosage of diuretic and digoxin needed, and decrease the re-admission frequency due to aggravation of heart failure.

KEY WORDS  Kanlijian, chronic heart failure, exercise tolerance, quality of life, aggravation of heart failure

In the last 20 years, the aim in the treatment of chronic heart failure (CHF) has been turned to intervene the pathogenesis of the disease, which, undoubtedly, is a revolutionary progress as compared with the treatment used in the past which simply aimed at hemodynamic disorders. However, the mortality of the patients with CHF is still high and the quality of life still low. Furthermore, the application of some Western medicine is limited to a great extent owing to their side-effects.

Along with the increasing of intervention with Chinese herbs in treating CHF, the combined treatment with traditional Chinese medicine (TCM) and Western medicine of CHF patients has presented its prominent superiority, though creditable efficacy assessment is still lacking.

This study aims to assess the effects of Kanlijian (坎离煎, KLJ), a Chinese herbal preparation made on the basis of a proven TCM recipe, in respect of short-term efficacy (including the alleviation of symptoms and syndromes, etc.), long-term follow-up outcome (including quality of life and exercise
tolerance of patient, etc.), part of the endpoint indexes (frequency of heart failure aggravation) as well as the reducing/withdrawal ratio of Western medicine in patients with CHF. Also it attempts to primarily set up an efficient assessment system of TCM therapy for CHF.

**METHODS**

**Diagnostic Criteria**

Heart failure was diagnosed according to the Framingham standard\(^{1}\). The grade of heart function was classified in reference to NYHA standard\(^{2}\). The TCM syndrome of Xin (心)-Shen (神) Yang deficiency was differentiated according to the "Guidance Principle of Clinical Research on New Drugs of TCM"\(^{3}\).

**Clinical Materials**

All the 60 patients with CHF enrolled were in-patients or out-patients at the department of cardiovascular diseases, Shanghai Shuguang Hospital, Shanghai from Jan. 2001 to Oct. 2004. They were randomly assigned according to the random number table into two groups at the ratio of 2:1, i.e., 39 patients in the KLJ group and 21 in the control group. The baseline characteristics of the two groups (gender, age, NYHA grade and previous medication, etc.) had no significant difference (\(P > 0.05\)), and so they were comparable. See Table 1.

**Treatment**

All patients in the two groups were treated according to the principle of using "angiotensin-converting enzyme inhibitor (ACEI), \(\beta\) receptor-blocking agents, diuretic, with or without digoxin", proposed in "Suggestion for Treatment of Chronic Systolic Heart Failure" issued by the cardiovascular branch of Chinese Medical Association, 2002 \(^{4}\), with Western drugs selected according to the patients' heart function, including Acertil, Betaloc, Hydrodiuril, with or without digoxin. To patients in the KLJ group, one dose of KLJ (consisting of Astragalus membranaceus Bge., Radix Aconiti lateralis, Semen Lepidii seu Descurainiae, Rhizoma Atractylodes, Radix Paeoniae, Poria, and Rhizoma Spar gangii, etc.) was given additionally, with 200 ml (containing 3.9 crude drugs/ml) divided and taken in two portions a day orally 2 h after meal. The therapy was continued for 24 weeks, and one year follow-up study was carried out.

**Items and Methods of Observation**

1. Scores of TCM symptoms and signs

Following "Guidance Principle of Clinical Research on New Drugs of TCM"\(^{3}\), the scores from 0 point to 3 point were given to the subjects in term of such main TCM syndrome as (1) shortness of breath during motion, (2) fatigue and listlessness, (3) oliguria and edema, (4) chest oppression, (5) palpitation, and (6) prominent jugular vein. For each of the above-mentioned items of syndrome zero point was given for absence of any syndrome, 1 for mild degree, 2 for moderate and 3 for severe.

2. Six-minute walking distance (6MWD)

With Peters's method adopted\(^{5}\), 6MWD in patients was measured.

3. Quality of life

Based on LHFQ assessment scale\(^{6}\).

4. Grade of heart function

Referring to NYHA classification\(^{2}\).

5. Hemodynamic indexes

Left ventricular ejection fraction (LVEF),

<table>
<thead>
<tr>
<th>Group</th>
<th>(n)</th>
<th>Age (yrs, x ± s)</th>
<th>Gender (Cases)</th>
<th>NYHA Class (Cases)</th>
<th>Baseline Therapy (Cases)</th>
</tr>
</thead>
<tbody>
<tr>
<td>KLJ</td>
<td>39</td>
<td>64.2 ± 10.4</td>
<td>19/20</td>
<td>33/6</td>
<td>ACEI 26 21 β-B 13 Diuretic 17 Digoxin 17</td>
</tr>
<tr>
<td>Control</td>
<td>21</td>
<td>68.9 ± 7.9</td>
<td>9/12</td>
<td>19/2</td>
<td>ACEI 39 26 β-B 12 Diuretic 21 17</td>
</tr>
</tbody>
</table>

Notes: ACEI: angiotensin-converting enzyme inhibitor; \(\beta\)-rB: \(\beta\) receptor-blocking agents