Effectiveness of Chinese herbal medicine Ping Chuan Ke Li for the management of mild/moderate persistent asthma

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Abstract
This study assessed the effectiveness and safety of Chinese herbal medicine Ping Chuan Ke Li (PCKL) for the treatment of patients with mild/moderate persistent asthma.

A total of 108 eligible patients with persistent asthma were included and were divided into a treatment group and a control group in this retrospective study. All 108 patients underwent oral montelukast. Additionally, subjects in the treatment group also received PCKL therapy. All patients in both groups were treated for a total of 1 month. The primary outcome of lung function was evaluated by the forced expiratory volume in one second (FEV1) and FEV1/forced vital capacity (FVC). The secondary outcome of quality of life was assessed by St. George’s Respiratory Questionnaire (SGRQ). Moreover, adverse events (AEs) were also recorded in this study. All outcome measurements were assessed after 1-month treatment.

After 1-month treatment, patients in the treatment group did not demonstrate better outcome in the improvement of lung function, measured by FEV1 (P = 0.57, table 2), and FEV1/FVC (P = 0.29); and enhancement of quality of life, measured by SGRQ scale (total, P = 0.37; symptom, P = 0.32; activity, P = 0.39; impact, P = 0.83). In addition, no AEs differ between 2 groups.

The results of this study showed that Chinese herbal PCKL may not benefit patients with mild/moderate persistent asthma after 1-month treatment.

Abbreviations: AEs = adverse events, CM = complementary medicine, FEV1 = forced expiratory volume in one second, FVC = forced vital capacity, PCKL = Ping Chuan Ke Li, SGRQ = St. George’s Respiratory Questionnaire.

Keywords: asthma, effectiveness, Ping Chuan Ke Li, safety

1. Introduction
Asthma is a heterogeneous respiratory disease, and it is associated with airway inflammation.[1–3] Its symptoms mainly include difficult breath, triggers coughing, wheezing, and shortness of breath.[4–5] Its prevalence rate was reported about 4.3%, with range from 0.7% to 21.0% around the world, while this figure was 1.24% in China.[6–7] It has been reported about 240 million people suffer from this condition worldwide.[8] It is estimated that this number will increase to 400 million by 2025.[9]

Inhaled corticosteroids (ICS) are reported to the main option for asthma treatment; and are highly effective for managing the asthma symptoms and also help to reduce the risk of asthma-related exacerbations, hospitalizations and death.[10–12] On the other hand, severe adverse events (AEs) with maintenance ICS treatment remain a tricky issue and it is also reported to be associated with poor asthma-related outcomes.[13–14] Therefore, more effective and safety treatment options are still needed to be explored.

Complementary medicine (CM) is a 1 of the most powerful potential candidates. It has been reported CM may be utilized to treat this condition effectively.[15–16] This kind of treatment option includes Chinese herbal medicine, acupuncture, moxibustion, yoga, exercise, and so on.[17–23] Although these options are widely recommended by the physicians, there is still insufficient evidence to support CM for treating patients with asthma. Therefore, more evidence is urgently needed to be conducted in CM for asthma.

Ping Chuan Ke Li (PCKL) is reported to treat asthma in the past decades without severe AEs.[17,24–25] However, limited data are available to support its effectiveness and safety of PCKL for treating patients with asthma presently, especially for persistent asthma. In this retrospective study, we explored the effectiveness and safety of PCKL for the treatment of patients with mild/moderate persistent asthma.
2. Methods

2.1. Study design

This study was approved by the Medical Ethics Committee of The First Affiliated Hospital of Heilongjiang University of Chinese Medicine. All the patient cases were selected between August 2015 and November 2017. Additionally, all patients provided written informed consent.

In this retrospective study, 108 eligible patients with mild/moderate persistent asthma were included. All these patients were equally assigned to a treatment group or a control group according to the different treatment schedule they received. Patients in the treatment group underwent oral montelukast plus PCKL therapy, while subjects in the control group received oral montelukast alone. All patients in both groups received a total of 1-month treatment. After treatment, the data of lung function and quality of life were analyzed for the assessment of PCKL therapy.

3. Patients

All included patients had diagnosed as mild to moderate persistent asthma. They aged between 22 and 68 years old. However, cases were excluded if they had serious organs diseases, allergy to the medication use, or took steroid drugs and antiallergic agents 1 month before this study. In additionally, cases were also excluded if they had insufficient data.

3.1. Treatment schedule

All 108 patients in both groups received montelukast orally every night, 10mg daily for a total of 1 month. In addition, patients in the treatment group also underwent Chinese herbal medicine PCKL, 10 g/sachet, 2 sachets each time, twice daily for a total of 1 month. PCKL was provided by the Pharmacy of First Affiliated Hospital of Heilongjiang University of Chinese Medicine.

3.2. Outcome measurements

The primary outcome included lung function. It was assessed by forced inspiratory volume in 1 second (FEV₁) [27–28] and FEV₁/FVC [29–30]. The secondary outcome was quality of life. It was evaluated by the tool of St. George’s Respiratory Questionnaire (SGRQ). Additionally, any AEs were also documented in this retrospective study.

3.3. Statistical analysis

All data in this retrospective study were analyzed by the Statistical Package for the Social Sciences Software 17.0 (IBM Corp., Armonk, NY). The t test or Mann–Whitney rank sum test was utilized to analyze the continuous data, while Chi-square test was applied to analyze the discrete variables. P < .05 was regarded as statistically significant.

4. Results

A total of 108 eligible patients with mild/moderate persistent asthma were included in this retrospective study. All the outcome data and the variables of characteristics were analyzed in this study. As for characteristics, no significant differences were detected between 2 groups (Table 1).

5. Discussion

Previous animal studies reported that PCKL can be utilized to inhibit airway inflammation and remodeling in experimental asthma animals [31–33]. PCKL can be applied to reduce inflammatory cell infiltration in the lung tissue of asthmatic rats. In addition, it also can decrease bronchial mucosa and airway wall

### Table 1

| Characteristics               | Treatment group (n = 54) | Control group (n = 54) | P value |
|------------------------------|-------------------------|------------------------|---------|
| Mean age (year)              | 42.8 (11.2)             | 44.5 (12.4)            | .45     |
| Sex                          |                         |                        |         |
| Male                         | 32 (69.3)               | 35 (64.8)              | .64     |
| Female                       | 22 (40.7)               | 19 (35.2)              | —       |
| Duration of asthma (year)    | 9.7 (3.3)               | 10.5 (2.9)             | .18     |
| Asthma category              |                         |                        |         |
| Mild                         | 12 (22.2)               | 15 (27.8)              | .46     |
| Moderate                     | 42 (78.8)               | 39 (72.2)              | —       |
| BMI (kg/m²)                  | 26.6 (2.9)              | 27.3 (3.1)             | .23     |
| Smoking history              |                         |                        |         |
| Smokers                      | 18 (33.3)               | 25 (48.1)              | .46     |
| Non-smokers                  | 34 (66.7)               | 29 (51.9)              | .46     |
| Previous medications, n (%)  |                         |                        |         |
| Ipratropium                  | 31 (57.4)               | 27 (50.0)              | .64     |
| Albuterol                    | 20 (37.0)               | 24 (44.4)              | .52     |
| Prednisone                   | 29 (53.7)               | 26 (48.1)              | .10     |
| Fluticasone                  | 18 (33.3)               | 21 (38.0)              | .57     |
| Zafirlukast                  | 14 (25.9)               | 12 (22.2)              | .57     |
| Lung function                |                         |                        |         |
| FEV₁, % (predicted)          | 67.3 (13.9)             | 69.1 (14.4)            | .51     |
| FEV₁/FVC (reduced), % predicted | 2.8 (0.7)          | 2.6 (0.8)              | .17     |
| SGRQ                         | Total                   | 53.8 (13.6)            | 55.1 (14.5) | .63 |
| Symptom                      | 56.2 (12.9)             | 57.4 (13.3)            | .62     |
| Activity                     | 51.0 (15.7)             | 52.8 (15.1)            | .52     |
| Impact                       | 52.5 (16.0)             | 50.9 (16.8)            | .61     |

Data are presented as mean±standard deviation or number (%).

### Table 2

| Lung function                  | Treatment group (n = 54) | Control group (n = 54) | Difference | P value |
|-------------------------------|-------------------------|------------------------|------------|---------|
| FEV₁/FVC (reduced), % predicted | –0.8 (–1.2, –0.3)       | –0.6 (–1.0, –0.2)      | –0.2 (–0.5, –0.1) | .29     |
| FEV₁, % predicted             | 2.8 (1.5, 4.1)          | 2.3 (1.1, 3.7)         | 0.5 (0.2, 0.8) | .57     |

FEV₁ = forced expiratory volume in 1 second, FVC = forced vital capacity.
Impact of intervention can effectively alleviate symptoms of chronic asthma.

In this study, 72 patients with chronic asthma were included. The study aimed to assess the efficacy and safety of PCKL for the treatment of persistent asthma. The results indicated that PCKL may not be beneficial, although there was a relative small sample size.

In the present study, we included 108 patients specifically with mild/moderate persistent asthma. It investigated the effectiveness and safety of PCKL for the treatment of persistent asthma. The results of this study are consistent with the previous study, which specifically focused on the PCKL treatment for chronic asthma.

In this study, after 1-month treatment, patients in the treatment group showed neither the improvement of lung function, measured by FEV1 and FEV1/FVC nor the enhancement of quality of life, measured by SGRQ scale. The results indicated that PCKL may not benefit patients with mild/moderate persistent asthma after 1-month treatment.

This retrospective study has several following limitations. First, the treatment period is relatively short in this study, which is far less than the previous study, and may accounts for the negative results of this study. Second, the outcome results and AEs were the combination of PCKL and montelukast, but not the PCKL alone, although both the groups underwent the same dose of montelukast. Third, this retrospective study could not control the drug administration of patients as the prospective study. Finally, previous study specifically investigated the effectiveness of PCKL for patients with acute asthma, but on chronic asthma.

6. Conclusion

The results of this study demonstrated that PCKL may not provide promising effectiveness for mild/moderate persistent asthma after 1-month treatment.

**Author contributions**

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