Kanglaite Injection (KLT) in the Treatment of Chemotherapy Inefficacious Patients with Advanced Non-Small Cell Lung Cancer (NSCLC)

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Abstract

Objective: Observe the effect of Kanglaite (KLT) Injection on chemotherapy inefficacious cases with advanced non-small cell lung cancer (NSCLC). Methods: 32 NSCLC sufferers who had failed chemotherapy of cisplatin (DDP) with vindesin (VDS) were given KLT injection in a dose of 200ml/d by intravenous drip for 30 days. Results: 8 cases with partial response (PR, 25.0%), 21 with no change (NC, 65.6%) and 3 with progressive disease (PD, 9.4%). KPS increased by 20 scores on an average. Amount of peripheral T-cell subgroups CD3, CD4 and NK cells got increased whereas amount of CD8 cells was decreased. Higher ratio of CD4/CD8 was observed. And most patients demonstrated better mental status, appetite, sleeping state and pain was relieved with a response rate of 75% (12/16) after KLT treatment. No common chemotherapy related side effects such as gastrointestinal tract symptoms or bone-marrow inhibition occurred. There were very slight side effects. Conclusion: KLT injection had certain effects on NSCLC. It could improve patients' quality of life and be considered as a remedy to the chemotherapy inefficacious cases with NSCLC.

Key words: lung tumor/Chinese Traditional Medicine therapy, lung tumor /drug therapy, ratio of CD4 to CD8, KLT

Lung cancer is one of the common malignant tumors with a tendency of increase year by year. Lung cancer sufferers usually have lost their chance of operation when they go to hospital so chemotherapy becomes a major treatment for them. However, the response rate of chemotherapy for NSCLC is still low [1]. From February 1996 to December 1997 we applied Kanglaite (KLT) injection to 32 chemotherapy inefficacious cases with NSCLC with results reported below.

1. Patients and methods

1.1 Patients
21 male and 11 female patients aged 46-72 with an average of 56 were recruited into the trial. Pathological typing: 18 cases with squamous carcinoma and 14 adenocarcinoma. Clinical staging: 24 patients were in stage IIIb and 8 in stage IV. KPS varied from 40 to 80 with an average of 56. All patients had previously been treated with at least two courses of chemotherapy of cisplatin (DDP) with vindesin (VDS). The chemotherapy failures ones received the treatment of KLT Injection.

1.2 Methods
One month after chemotherapy the patients were given KLT Injection in a dose of 200ml/d by
intravenous drip once a day for 30 days as a treatment cycle. Blood routine, liver and kidney function, chest X-ray, CT and T-cell subgroups were examined before and after treatment. The therapeutic effect was evaluated according to the “Standard for Evaluation of the Therapeutic Effect on Solid Tumors” formulated by WHO\(^2\).

2. Results

8 patients in trial group got PR, 21 with NC and 3 with PD. KPS scores increased from the average of 56 before treatment to 76 after treatment. 8 of the 16 pain sufferers got partial relief and 4 complete relief with total response rate as 75% (12/16). Change of T-cell subgroups before and after treatment was shown in Table 1. Side effects were slight. Only 3 patients had transient low fever with body temperature ranging from 37.5°C to 38.2°C. There was no evident change in liver or kidney function before and after treatment and no bone-marrow inhibition was reported.

<table>
<thead>
<tr>
<th>Table 1. Change of T-cell subgroups before and after treatment (X ± SD)</th>
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<tr>
<td><strong>n=32</strong></td>
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<td>Before treatment</td>
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<td>After treatment</td>
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\(t\)-test, * \(P<0.01\)

3. Discussion

KLT Injection is an anticancer drug extracted from *coix* seed with effects of improving immune function and anticancer \(^3\). Clinical and experimental studies have demonstrated that it can inhibit and kill cancer cells, significantly improve the function of immune system, relieve toxic and side effects of radiotherapy or chemotherapy, provide high energy nutrition and have the effect of anti-cachexia \(^4\).

Clinical patients with lung cancer usually have lost their chance of operation when they go to hospital. Radiotherapy and chemotherapy are hyposensitive to NSCLC with poor therapeutic effect. Many serious side effects will appear. In those chemotherapy inefficacious patients, they would be difficult to tolerate new chemotherapy schemes or higher dosage due to their poor physical status. Therefore it is quite important to seek novel anticancer drugs with higher efficacy and safety.

In this trial 32 chemotherapy inefficacious patients with NSCLC were treated with KLT Injection by intravenous drip. 8 of them demonstrated PR, 21 with NC and 3 with PD. Most patients showed significant improvement in mental status, sleeping state, appetite and physical strength. Pain relief rate was 75.0% (12/16). Some patients had their pain relieved but therapeutic effects failed to reach the level of PR. 2 patients suffering from severe pains caused by bone metastasis got relieved in pain after treatment with KLT from the first week and the pain totally disappeared half month later. Through re-examination of CT and ECT the therapeutic effect did not reach PR level. This indicated that KLT Injection had remarkable effect on pain relief but its specific mechanism needed further studies. At the same time KPS score increased from an average of 56 before treatment to 76 after treatment. Level of CD3 and CD4 cells, ratio of CD4 to CD8 and activity of NK cells in peripheral blood were all elevated
notably. Compared with the data before treatment there existed extraordinary significant difference (P<0.01) indicating that immune function got improved. Through 3 cycles of KLT treatment, the focal lesion in one patient suffering from stage IIIb squamous carcinoma had been stable for 25 months though the therapeutic effect didn’t get PR. And this might be related with improvement of immune function to inhibit tumor growth. KLT Injection had quite slight side effect without bone-marrow inhibition. It was particularly applicable to patients who could not tolerate chemotherapy due to severe bone marrow depression and those who were not suitable for chemotherapy due to late stage cachexia. Therefore KLT Injection could be considered as a remedy therapy to the chemotherapy inefficacious patients with advanced NSCLC.

Reference