Clinical Efficacy of Kang’ai Injection Combined with Chemotherapy in Treating Advanced Cervical Cancer

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Abstract: Objective: To investigate the curative effect of Kangai injection combined with chemotherapy on advanced cervical cancer. Methods: 58 cases of advanced cervical cancer were randomly divided into two groups, observation group and control group, with 29 cases in each group. The control group was treated by conventional radiotherapy and chemotherapy. The observation group was given intravenous Kang’ai injection on the basis of radiotherapy and chemotherapy, and the treatment time was last for 4 weeks. According to the solid tumor evaluation criteria after the end of treatment to evaluate the short-term efficacy of patients, according to the Karnofskys performance scoring of patients with quality of life, and compared the two groups of patients treated by side effects. Results the effective rate of the observation group was 75.9%, while that of the control group was 44.8%. There was significant difference between the two groups (P <0.05), and the quality of life in the observation group was significantly better than that of the control group (P <0.01). The incidence of nausea and vomiting, leukopenia and abdominal pain in the observation group were significantly lower than those in the control group (P <0.05). Conclusions Kang’ai injection combined with chemotherapy in the treatment of advanced cervical cancer has obvious effect and little side-effect, which is a better choice for the treatment of advanced cervical cancer. It is worthy of clinical promotion.

Introduction

Cervical cancer is the most common female malignant tumor of the genital tract[1]. Cervical cancer often has no obvious symptoms at the early stage. When it is used for vaginal examination, it can only find superficial erosion. Once the corresponding symptoms appear, most of the patients have developed to the middle and late stage. The earliest symptoms of cervical cancer are vaginal bleeding and increased leucorrhea. The diagnosis can be made by cytological examination of cervix scraping film and biopsy of the cervix. The main treatments of cervical cancer are surgery and chemotherapy at present. Although there is some effect, the side-effects of the patients are serious, which seriously affect the quality of life of patients. Kang’ai injection containing traditional Chinese medicine ingredients, can inhibit the proliferation of tumor cells to a certain extent, and has good application value, the report is as follows
Materials and Methods

General Information

This study was approved by our hospital ethics committee, and patients signed an informed consent form. 58 patients with advanced cervical cancer who were diagnosed in China-Japan Union Hospital of Jilin University from January 2015 to December 2017. Following the strict inclusion and exclusion criteria, they were randomly divided into two groups equally, including 29 treated with chemoradiotherapy (Control group) and 29 with Kang’ai injection and chemoradiotherapy (Observation group). The age of the observation group was 34-65 years old, the median age was (44.23 ± 11.25) years old, there were 6 cases of adenocarcinoma, 7 cases of adenosquamous carcinoma, 16 cases of squamous cell carcinoma, 10 cases of stage IIIA, 9 cases of stage IIIB, 6 cases of stage IVA and 3 cases of stage IVB, confirmed by pathological examination, using FIGO staging. The control group was 32-63 years old, and the median age was (43.18 ± 18.22) years. There were 7 cases of adenocarcinoma, 7 cases of adenosquamous carcinoma, 15 cases of squamous cell carcinoma, 9 cases of stage IIIA, 8 cases of stage IIIB, 6 cases of stage IVA and 5 cases of stage IVB, confirmed by pathological examination, using FIGO staging. There was no statistical difference in age, pathological type and stages of the two groups, and was comparable (P>0.05).

Treatment Methods

The patients in the control group were treated with chemotherapy, the treatment prescription was as follows, take 30~50 mg/m2 of docetaxel and 50 ~ 80mg/m2 of cisplatin per time with intravenous injecting, once a week and lasted for 4 weeks. The observation group was treated with chemotherapy and Kang’ai injection therapy, Patients with intravenous infusion of Kang’ai injection in 30mg for each time, 1 times a day, until the end of chemotherapy.

Standard of Curative Effect and Evaluation Method

Before and after 1 week’s treatment, the size of the tumor was measured by Doppler ultrasound and CT examination, and the curative effect was evaluated according to the solid tumor evaluation standard formulated by WHO. Complete remission: the tumor completely disappeared; partial remission: tumor shrinkage degree > 50%; improvement: the tumor has narrowed, but the degree is less than or equal to 50%; no change: no change in tumor size; disease progression: progress in tumor. Efficiency=(complete remission number + partial remission number) / total number x 100%.

The Karnofsky’s performance scoring (KPS) is used to evaluate patients 3 months after treatment. Improvement: KPS increased is more than 10 points; stability: KPS is range within 10 points; deterioration: KPS decreased more than 10 points after treatment.

The incidence of side-effects during the treatment of two groups of patients were observed such as leukocyte descent, abdominal pain and nausea.

Statistical Methods

All data using SPSS 21.0 statistical software for processing, measurement data using mean and standard deviation (X±S) to represent. And paired t test for data comparation between two groups, P <0.05 considered statistically significant.
Result

Comparison of Effect after Treatment in Two Groups of Middle and Advanced Cervical Cancer Patients

The effective rate of the patients in the observation group was higher than that of the control group (75.9% to 55.2%) ($x^2$ = 4.324, $P < 0.05$). (Table 1.)

Table 1. Comparison of effect after treatment in two groups of middle and advanced cervical cancer patients [Case NO. (%)].

<table>
<thead>
<tr>
<th>Group</th>
<th>Case number</th>
<th>Complete remission</th>
<th>Partial remission</th>
<th>Improvement &amp; No change</th>
<th>Disease progression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation group</td>
<td>29</td>
<td>10(34.5)</td>
<td>12(41.4)</td>
<td>4(13.8)</td>
<td>3(10.3)</td>
</tr>
<tr>
<td>Control group</td>
<td>29</td>
<td>7(24.1)</td>
<td>9(31.0)</td>
<td>8(27.6)</td>
<td>5(17.2)</td>
</tr>
</tbody>
</table>

Comparison of the Improvement of Quality of Life in Two Groups of Patients with Advanced Cervical Cancer after Treatment

After treatment, the improvement of quality of life in the observation group was better than that of the control group, and the difference was statistically significant ($Z = 11.58$, $P < 0.01$). (Table 2.)

Table 2. Comparison of the improvement of quality of life in two groups of patients with advanced cervical after treatment. [Case NO. (%)].

<table>
<thead>
<tr>
<th>Group</th>
<th>Case number</th>
<th>Improvement</th>
<th>Stability</th>
<th>Deterioration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation group</td>
<td>29</td>
<td>22(75.9)</td>
<td>5(17.2)</td>
<td>2(6.9)</td>
</tr>
<tr>
<td>Control group</td>
<td>29</td>
<td>13(44.8)</td>
<td>9(31.0)</td>
<td>8(27.6)</td>
</tr>
</tbody>
</table>

Table 3. Comparison of side effects of two groups of patients with advanced cervical cancer after treatment. [Case NO. (%)].

<table>
<thead>
<tr>
<th>Group</th>
<th>Case number</th>
<th>leukocyte decline</th>
<th>abdominal pain</th>
<th>nausea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation group</td>
<td>29</td>
<td>13(44.8)</td>
<td>12(41.4)</td>
<td>10(34.5)</td>
</tr>
<tr>
<td>Control group</td>
<td>29</td>
<td>22(75.9)</td>
<td>20(69.0)</td>
<td>18(62.1)</td>
</tr>
<tr>
<td>$X^2$</td>
<td>4.386</td>
<td>3.865</td>
<td>4.026</td>
<td></td>
</tr>
<tr>
<td>$P$</td>
<td>0.037</td>
<td>0.034</td>
<td>0.041</td>
<td></td>
</tr>
</tbody>
</table>
Comparison of Side-effects of Two Groups of Patients with Advanced Cervical Cancer after Treatment

After treatment, the incidence of leukocyte decline, abdominal pain and nausea in the observation group were significantly lower than those in the control group (P<0.05), and the difference was statistically significant (Table 3).

Discussion

Cervical cancer is currently the second most of common cancer in women, and the fifth most of common cancer in women on death rate [2-3]. According to statistics, the number of new cervical cancer patients has 1.6/10000 increment rate annually[4]. At present, the treatment of early cervical cancer is mainly by surgery, while the advanced cervical cancer is based on synchronous radiotherapy and chemotherapy. Because the advantaged tumor invaded normal tissue and destroyed the defense ability, the immune function of the body is reduced completely.

After radiotherapy and chemotherapy, it can cause a series of side effects: (1) the patient shows series of disorders such as dizziness, loss of appetite, body weakness, fatigue, nausea and vomiting.(2) Side effects of chemotherapy for cervical cancer: oral mucosal hyperemia, hemorrhage, extreme erosion, ulcer, fused into the tunica albuginea, purulent secretion, pain, and occasionally fever. The oropharynx was flecked with white, hyperemia and edema, ulceration, pain, dysphagia [5]. Dry skin is characterized by itching, pigmentation and desquamation, which can produce a permanent light brown spot. Wet skin is manifested by eczema and blisters in the irradiated area, which can cause erosion and damage in severe cases.

These toxic and side effects give cervical cancer patients a different degree of pain, and even affect the progress of the treatment, making the patient’s condition deteriorated. Because of many toxic and side effects of radiotherapy and chemotherapy, it can affect the therapeutic effect and quality of life of patients. Therefore, we are actively looking for ways to enhance the effect of radiotherapy and chemotherapy and reduce side effects. In clinical work, there have been many reports about the effect of Chinese herbal medicine on improving the quality of life and enhancing the curative effect of patients. The application of Ginseng Polysacchride Injection combined with chemotherapy in the treatment of cervical cancer can improve the curative effect, improve the quality of life. Reduce the effect of chemotherapy and side effects.

Kang’ai consists mainly of astragalus, ginseng, radix sophorae flavescentis etc. Ginsenoside Rg3 is the main active ingredients of ginseng, clinical studies have demonstrated that promote tumor cell apoptosis, inhibit tumor cell proliferation, invasion and metastasis and tumor angiogenesis. While combined use of ginsenoside and chemotherapy, it can sensitizing chemotherapy effect, and the mechanism may be related to the inhibition of NF- Beta Kappa activity. The latest anti-tumor mechanism of astragalus suggests that astragalus can enhance the function of T lymphocytes and increase CD4 and CD4/CD8, thereby playing a role in regulating the immune function of cancer patients[6]. Large dose of Astragalus can promote the induction and generation of peripheral blood mononuclear cells, increase the number of dendritic cells and enhance the antigen-presenting function of dendritic cells in patients with acute leukemia[7]. The main application of Astragalus is to improve the immune function of the body, protect and promote the hematopoietic ability of bone marrow, and enhance the tumor activity of immune cells. The combination of Astragalus and chemotherapeutic drugs can reduce the toxic and side effects of chemotherapy, improve the effect of chemotherapy,
and increase the patient’s tolerance to surgery, radiotherapy, or chemotherapy, also can promote the recovery of immune function after operation, and the cure rate, the quality of life of the patients. Xuan Lijun [8] believed that the application of compound Marine Injection with chemotherapy in the treatment of malignant tumors, although not significantly increase the curative effect, it can obviously alleviate the side effects of chemotherapy and improve patient tolerance to chemotherapy.

According to the research, Kang’ai injection can inhibit the proliferation of tumor cells, reduce the toxicity of chemotherapy. Ginseng can reinforce vital energy effect, help produce saliva and slake thirst, peace the mind and enhance the intelligence; Astragalus has a lot of curative effect, such as, tonifying Qi and lifting Yang, strengthening exterior and reducing sweat; radix sophorae flavescentis has the effect of clearing heat and detoxifying, eliminating swelling and dispersing stasis[9]. Kang’ai injection can directly kill cancer cells; cut off the synthesis of DNA molecular chain in cancer cells, inhibit the growth of cancer cells; enhance immunity. The study found that there was significant difference in bone marrow suppression in the two groups.

This study shows that, compared with only chemotherapy, combined with Kang’ai injection in the treatment of advanced cervical cancer has obvious effect, low incidence of side-effects, can significantly improve the patients’ quality of life. Therefore, the combination usage of Kang’ai injection and chemotherapy is one of the best choices for the treatment of advantaged cervical cancer.

Reference


