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CLINICAL STUDY

Integrated Chinese-western therapy versus western therapy alone on survival rate in patients with non-small-cell lung cancer at middle-late stage

Guoqiang Lin, Yingqiu Li, Shengxi Chen, Haihe Jiang

Guoqiang Lin, Haihe Jiang, Shengxi Chen, Xiangya Hospital, Xiangya Medical College Zhongnan University, Changsha 410008, China
Yingqiu Li, College of Basic Medicine, Hunan University of Traditional Chinese Medicine, Changsha 410007, China
Correspondence to: Prof. Haihe Jiang, Xiangya Hospital, Xiangya Medical College Zhongnan University, Changsha 410008, China. lingq1977@126.com
Telephone: +86-10-15501050756
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Abstract

OBJECTIVE: To compare the effects of integrated Chinese-Western therapy versus Western therapy alone on the survival rate of patients with non-small-cell lung cancer (NSCLC) at middle-late stage and to evaluate prognostic factors.

METHODS: We selected 98 inpatients with middle-late stage NSCLC diagnosed from March 2009 to March 2011 and randomly divided them into two groups, with 49 cases in each group, and the clinical data were analyzed retrospectively. The control group was treated by the combined methods of Western Medicine, including chemotherapy, supportive treatment and symptomatic treatment. The observation group was treated by injection and prescriptions of Chinese medicine based on Traditional Chinese Medicine syndrome differentiation and by the same combined methods of western treatment used in the control group. After treatment, the survival rates of the patients were compared by the stage of cancer and evaluation of 24 prognostic factors analyzed by a Cox regression model, and the clinical data were statistically analyzed.

RESULTS: The survival rates of all patients were over 90.0% at 1 and 3 months after treatment with no significant differences between the two groups ($P>0.05$); In the observation group the survival rates at 6 months and 1 year were 93.4% and 42.8%, respectively, being superior to 85.6% and 18.3% in the control group ($P<0.05$). The median survival time in the observation group was superior to the control group ($P<0.05$); The effects of 24 prognostic factors were significantly better in the observation group than in the control group ($P<0.05$).

CONCLUSION: Integrated Chinese-western therapy can significantly improve the survival rate in patients with middle-late stage NSCLC and improve prognostic factors compared with western therapy alone.

Key words: Carcinoma, non-small-cell lung; Syndrome differ treatment; Medicine, Chinese traditional; Chemotherapy; Prognosis

INTRODUCTION

Non-small-cell lung cancer (NSCLC) is a malignant tumor of the lung with a high mortality rate. It accounts for 80% of total lung cancers, which mainly include adenocarcinoma, squamous cell carcinoma of the lung, and large cell undifferentiated carcinoma. Because of

the poor sensitivity of routine chemotherapy to this disease, the mortality is higher than other lung carcinom. Middle-late stage patients are not suitable for operative treatment, and routine chemotherapy has poor sensitivity, leading to a higher death rate.[1] Studies on treatment methods and the clinical therapeutic effects of middle-late stage NSCLC have become an area of great interest in clinical research.[2,10] At present, therapeutic methods for middle-late stage NSCLC include chemotherapy, radiotherapy, immunotherapy, biotherapy, Traditional Chinese Medicine (TCM) treatment, but the long-term therapeutic effects are not ideal. Clinical studies confirm that TCM syndrome differentiation treatment combined with chemotherapy can increase the long-term therapeutic effect on middle-late stage NSCLC by increasing the effect of protective factors, thus prolonging survival times.[3,11] In our hospital, TCM syndrome differentiation treatment combined with chemotherapy and simple western treatment were used for treatment of middle-late stage NSCLC, and the clinical data were compared.

MATERIALS AND METHODS

This study was conducted on patients diagnosed with middle-late state NSCLC at Xiangya Hospital, Changsha, China from March 2009 to March 2011.

Inclusion and exclusion criteria

The inclusion and exclusion criteria were those stipulated in the Newly Compiled Standards for Diagnosis and Treatment of Commonly-seen Malignant Tumor and Guiding Principle of Clinical Studies of New Chinese Drugs compiled by the China Anti-cancer Association.

Inclusion criteria: (a) patients conformed to diagnostic criteria for NSCLC in Newly Compiled Standards for Diagnosis and Treatment of Commonly-seen Malignant Tumor and were middle-late stage in clinical staging; (b) before treatment, patients had not received radiotherapy and chemotherapy; (c) except for cancer of the lung, critical lesions of the kidney and other important organs were not present; (d) patients had no allergic history or contraindication to use of the drugs used in the study.

Exclusion criteria: (a) patients with high blood pressure, diabetes and other chronic diseases with a weak constitution who were thus unable to receive chemotherapy; (b) patients with a mental or sensory disturbance, who were unable to accurately describe their symptoms; (c) women who might become pregnant or who were breastfeeding; (d) patients who did not want to participate in the research or lacked clinical data.

Treatment methods

After admission, the patients were treated with routine clinical therapy for inflammation, for relief of cough and asthma, analgesia, expectant treatments, and nutrition support. Corresponding treatments were given to the control group and the observation group.

For the control group, the patients were treated with chemotherapy: (a) squamous cell carcinoma: drugs: cyclophosphamide (Jiangsu Hengrui Medicine Co. Ltd., H32024654, Jiangsu, China), adriamycin (Zhejiang Haizheng Pharmaceutical Co. Ltd., Zhejiang, China), cisplatin injection (Jiangsu Haoshen Pharmaceutical Co. Ltd., H20040813, Jiangsu, China); Administration and dosage: according to the CAP treatment program: venous injection of cyclophosphamide 600 mg/m^2 and adriamycin 50 mg/m^2 each day, and continuous intravenous infusion of cisplatin 80 mg/m^2; course of treatment: continuous administration for 3-4 weeks was regarded as one cycle, and after resting for 1-2 days, the treatment was continued, with two cycles constituting one course. (b) Adenocarcinoma: drugs: etoposide podo-ethylidene (Shandong Qilu Pharmaceutical Co. Ltd., H37023183, Shandong, China), cisplatin injection (Jiangsu Haoshen Pharmaceutical Co. Ltd., H20040813, Jiangsu, China); administration and dosage: According to the EP program, continuous venous infusion of podo-ethylidene glycoside 100 mg/m^2 each day for 3 days, continuous venous infusion of cisplatin injection 80 mg/m^2 each day;[3] course of treatment: continuous administration for 3-4 weeks constituted one cycle and after a rest of 1-2 days, the treatment was continued, with two cycles constituting one course; (c) Magnocellular undifferentiated carcinoma: drugs: taxol injection (Yangzhou Aosaikang Pharmaceutical Co. Ltd., H20043121, Yangzhou, China), carboplatin injection (Qilu Pharmaceutical Co. Ltd., H20020181); administration and dosage: According to the chemotherapy treatment program, continuous venous infusion of taxol injection 135 mg/m^2 each day, continuous venous infusion of carboplatin injection 300 mg/m^2 each day; continuous administration for 4 weeks constituted one cycle. After a rest of 1-2 days, the treatment was continued. Two cycles of the treatment constituted one course of treatment.

For the observation group, the patients were treated by injection of Chinese medicines and Chinese medical descriptions according to the TCM syndrome types on the same basis as treatment given to the control group.

Treatment with Chinese Medicine injections: Intravenous injection of coixenolide, 200 mL/d, or Aidi Injection composed of Banmao (*Mylabris Phalerata*), Renshen (*Radix Ginseng*), Huangqi (*Radix Astragali Mongolici*), Ciwujia (*Radix et Caulis Acanthopanacis Santicosi*), 40 mL/d.[4]

Syndrome differentiation treatment: (a) for type of *Qi*-deficiency and phlegm-dampness, Huangqi (*Radix Astragali Mongolici*) 30 g, Chenpi (*Pericarpium Citri Reticulatae*) 6 g, Banxia (*Rhizoma Pinelliae*) 15 g, Dangshen (*Radix Codonopsis*) 20 g, Fuling (Poria) 20 g, Gualou (*Fructus et Semen Trichosanthis Kirilowii*) 15 g, Baizhu (*Rhizoma Atractylodis Macrocephalae*) 15 g, Zhigancao (*Radix Glycyrrhizae Preparata*) 6 g; (b) for type of

Yin-deficiency and interior heat, Maidong (*Radix Ophiopogonis Japonici*), Shashen (*Radix Adenophorae Strictae*), Jinyinhua (*Flos Lonicerae*), Yejuhua (*Flos Dendranthematis Indici*), Pugongying (*Herba Taraxaci Mongolici*), Banzhilian (*Herba Scutellariae Barbatae*) and Baihausheshecao (*Herba Hedyotis*) 30 g each, and Tianhuafen (*Radix Trichosanthis*) 18 g, Shenggancao (*Crude Radix Glycyrrhizae*) 6 g; (c) For deficiencies of both *Qi* and *Yin*, Taizishen (*Radix Pseudostellariae*) 30 g, Maidong (*Radix Ophiopogonis Japonici*) 30 g, Shenghuangqi (Crude *Radix Astragali Mongolici*), Dangshen (*Radix Codonopsis*), Huaishan yao (*Rhizoma Dioscoreae Oppositae*) and Fuling (Poria) 20 g each, Wuweizi (*Fructus Schisandrae Chinensis*) 10 g, Baizhu (*Rhizoma Atractylodis Macrocephalae*) 15 g, Sangshen (*Fructus Mori*) 15 g; (d) For type of *Qi*-stagnation and blood stasis, Mudanpi (*Cortex Moudan Radicis*), Shengtaoren (*Semen Persicae*), Xiangfu (*Rhizoma Cyperi*), Jianghuang (*Rhizoma Curcumae Longae*), Yanhusuo (*Rhizoma Corydalis*) and Chuanqiong (*Rhizoma Chuanxiong*)15 g each, Caihu (*Radix Bupleuri*), Ezhu (*Rhizoma Zedoariae*), Zhiqiao (*Fructus Aurantii*), Jiegeng (*Radix Platycodi*) 12 g each, Quanxie (Scorpio) 6 g, Wugong (Scolopendra) 4 pieces; (e) For type of fire-toxicity, Yiyiren (*Semen Coicis*) 30 g, Weijing (Reed Stem) 30 g, Huangqin (*Radix Scutellariae*) 30 g, Taoren (*Semen Persicae*) 15 g, Zhebeimu (*Bulbus Fritillariae*) 12 g, Dongguaren (*Semen Benincasae*) 20 g.[5,6]

Modification of the prescription in accordance with symptoms: (a) for sustained fever, Shengshigao (*Gypsum Fibrosum*) 12 g, Daqingye (*Folium Isatidis*) 15 g, Shuiniujiao (*Cornu Bubali*) 9 g or Chaihu Zhenji, Qingkailing injection were added; (b) for phlegm with blood: Baimaogen (*Rhizoma Imperatae*) 12 g, Oujie (*Nodus Nelumbinis Rhizomatis*) 12 g, Sanqifen (powder *Radix Notoginseng*) 9 g, Hanliancao (*Herba Ecliptae*) 15 g, Baijifen (powder *Rhizoma Bletillae*) 15 g were added; (c) For patients with back pain, pain of Chest throx, Moyao (Myrrha) 12 g, Chuanwutou (*Radix Aconiti*) 6 g, Yanhusuo (*Rhizoma Corydalis*) 9 g, Sanqifen (powder *Radix Notoginseng*) 9 g were added; (d) for fluid retention in the hypochondrium, fullness and oppressed sensation in chest: Shanglu (*Radix Phytolaccae*) 9 g, Tinglizi (*Semen Lepidii seu Descurainiae*) 12 g, Dazao(*Fructus Jujubae*) 6 pieces, Cheqiancao (*Herba Plantaginis*) 9 g were added.

All the injectable drugs and Chinese herbal pieces were supplied by the TCM pharmacy of our hospital and purchased from the market according to the Drug Purchasing Principle.

Each dose of the Chinese drug was added to 300 mL of water and immersed for 30 min, and decocted with slow fire soft fire for 30-60 min into about 150 mL and administrated warmly. One dose each day was divided into two parts taken in the morning and evening; 4 weeks constituted one cycle and two continuous cycles constituted one therapeutic course.

Indices and methods of observation

Survival rate: Follow-up was from September 2009 to March 2012, and the follow-up data were analyzed retrospectively. The survival data of the two groups at 6 months and 1 year were counted, and the survival time was calculated by the Kaplan-Meier method (survival rate=survival cases/total cases ×100%).

Establishment of prognostic factors:

The research data were evaluated by a Cox regression model as follows:

Effective factor (Y): the survival period was calculated by the Kaplan-Meier method.

Establishment of variable factors (X):

Host factors: (a) age: age <40 years was marked 1, between 40-49 years 2, between 50-59 years 3, 60-69 years 4, >70 years 5; (b) sex: male was marked 1, female 0; (c) smoking: smoking was marked 1, non-smoking 0; (d) hemoglobin: hemoglobin count < 110 g/L was marked 0, >110 g/L 1; (e) serum calcium: serum calcium concentration <2.75 mmol/L was marked 0, over 2.75 mmol/L 1; (f) carcinoembryonic antigen: <30 mg/mL was marked 0, more than 30mg/mL 1; (g) CA19-9: <33 U/mL was marked 0, >33 U/mL 1; (h) Lactic dehydrogenase: <245 IU/L was marked 0, >245 IU/L 1; (i) TCM syndrome classification: Extreme accumulation of noxious heat was marked 1, *Qi* stagnation and blood stasis 2, *Qi* deficiency and phlegm dampness 3, deficiency of both *Qi* and *Yin* 4, interior heat due to *Yin* deficiency 5; (j) Karnofsky score before treatment: 70 before treatment was marked 1, 80 was marked 2, 90 was marked 3.[7]

Tumor factors: (a) tumor types: magnocellular undifferentiated carcinoma was marked 1, squamous cell carcinoma 2, adenocarcinoma 3; (b) position of primary focus: peripheral type was marked 0, central type 1; (c) clinical staging: stage IIIA was marked 1, stage IIIB 2, stage IV 3; (d) necrotic degree of tumor: tumor with cavity was marked 1, with no cavity 0; (e) Lymph code: affection was marked 1, no affection 2;

Treatment methods factors: western treatment was marked 1, integrated Chinese-western treatment 2.[8]

Response to treatment factors (CR: complete response, PR: partial response, NC: no change): effectiveness: CR+ PR, effectiveness was marked 1, ineffectiveness 0; stability: CR + PR + NC, maintaining stabilization was marked 1, advance 0; total cumulative score in the survival scale after treatment: no increase was marked 0, increase 1; CD3+: increase was marked 1, no increase 0; CD4 + : no increase was marked 0, increase 1; CD8+: no increase was marked 0, increase 1; CD4+/CD8+: increase was marked 1, no increase 0.[9]

Statistical method

The data were analyzed by SPSS version 15.0 (SPSS Inc., Wacker Drive, Chicago, IL, USA) statistical software. $P<0.05$ was regarded as a significant difference.

RESULTS

Ninety-eight patients with middle-late stage NSCLC were selected from patients treated between March 2009-March 2011 according to the inclusion and exclusion criteria, and divided into a control and observation group, with 49 cases in each group. In the observation group, 31 cases were male and 18 were female, aged between 38-78 years, with a mean (standard deviation) of (64±3) years; 18 cases had adenocarcinoma, 22 had squamous cell carcinoma, and 9 cases had magnocellular undifferentiated carcinoma; 10 cases were at stage IIIA, 13 cases were at stage IIIB and 26 cases were at stage IV. Karnofsky scores in 16 cases were 70, in 18 cases were 80, and in 15 cases were 90. In the control group, 33 cases were male and 16 cases were female, aged between 39-76 years, with a mean (standard deviation) of (63±5) years; 19 cases had adenocarcinoma, 23 cases had squamous cell carcinoma, and 7 cases had magnocellular undifferentiated carcinoma; 11 cases were at stage IIIA, 14 cases were at stage IIIB and 24 cases were at IV. Karnofsky scores in 15 cases were 70, in 20 cases were 80 and in 14 cases were 90. There were no significant differences between the two groups in sex, age, lesion types, clinical staging and Karnofsky score (P>0.05).

Comparison of survival rates

The survival rates in all of the subjects were over 90.0% at 1 and 3 months, with no significant differences between the two groups (P>0.05); In the observation group the survival rates at 6 months and 1 year were 93.4% and 42.8%, respectively, being superior to 85.6% and 18.3% in the control group, a significant difference (P<0.05); For the comparison of the median survival rate, the observation group was superior (386±12) to the control group (258±8) with a significant difference.

Analysis of prognostic factors

The effects of 24 potential prognostic factors were analyzed and compared by Cox single-analysis and Cox multi-analysis models. The effects of protective factors in the observation group were superior to those in the control group (P<0.05). Analysis of the effects of 24 prognostic factors using the Cox single analysis model showed that factors with a regression coefficient $\beta > 0$, indicated poor survival, and when $\beta < 0$, factors were considered protective. Age, clinical staging, lymph node affected, degree of necrosis of the tumor, complications, TCM syndrome classification, serum calcium, lactic dehydrogenase, carcinoembryonic antigen, CA199 and CD8+ were high-risk factors. While Karnofsky score before treatment, hemoglobin, total score on the survival scale after treatment, effectiveness after treatment, stabilization after treatment, CD3+, CD4+, CD4+/CD8+ were protective factors; The variables in the single analysis were added into the Cox multi-analysis model, and the effects of prognostic factors on survival rate was evaluated and analyzed according to the regression coefficient β value. Karnofsky score before treatment, treatment method, total score on the survival scale after treatment, stability of treatment and CD3+ were protective factors in prognosis; clinical staging, lymph node affected, complication, TCM syndrome classification, lactic dehydrogenase, carcinoembryonic antigen and CA199 were risk factors for prognosis (Table 1).

DISCUSSION

TCM syndrome differentiation treatment combined with chemotherapy improved survival time for middle-stage patients and the long-term survival rate was greater than with simple chemotherapy (P<0.05). The effects of the 24 prognostic factors were analyzed with Cox single-analysis. Age was a high-risk factor.[12] The lymph node affected, clinical staging, complications, necrotic degree of tumor, serum calcium, TCM syndrome classification, carcinoembryonic antigen, lactic dehydrogenase, CA199 and other tumor factors were risk factors, the higher the degree, the higher the risk; the poorer the prognosis, the higher the death rate. Hemoglobin and Karnofsky score before treatment were protective factors; the higher they were, the better the prognosis.[13] Improving the treatment method can effectively increase the clinical therapeutic effect and decrease the clinical death rate.[14] The total cumulative score of survival scale after treatment, effectiveness after treatment, treatment stability, and CD3+, CD4+, CD4+/ CD8+ counts were protective factors, which can be increased by corrective methods, to improve the clinical therapeutic effect. CD8+ is a risk factor.[15,16] From the Cox multi-analysis model the Karnofsky score before treatment, treatment methods, total cumulative score of survival scale after treatment, treatment stability and CD3+ were protective factors in prognosis.[17] Clinical staging, lymph code affected, complications, TCM syndrome classification, lactic dehydrogenase, carcinoembryonic antigen and CA199 were risk factors for prognosis.

Treatment methods can be improved based on the effects of various prognostic factors to increase protective factors and decrease risk factors, thus further improving the clinical therapeutic effect. The results of a study on influencing prognostic factors in middle-late stage NSCLC can be regarded as criteria for assessment of the therapeutic effects of treatment methods and indices of prognosis. These data are also an important basis for researching new therapy. Therefore, studies on the effects of prognostic factors have important clinical value.

TCM syndrome differentiation therapy can not only inhibit the increase in cancer cells and treat complications, but also alleviate side effects induced by chemo-

Table 1 Analysis of Cox model

Factor	Single-analysis of Cox model			Multi-analysis of Cox model		
	Regression coefficient (β)	Score (Wald)	*P*	Regression coefficient (β)	*P*	Relative Hazard severity [Exp (β)]
Age	0.221	3.321	0.000	0.023	0.901	1.103
Sex	-0.040	0.033	0.867	-0.358	0.176	0.564
Smoking	-0.312	1.627	0.221	-0.159	0.759	0.783
Pathology	0.102	0.435	0.569	0.138	0.425	1.323
Clinical staging	1.121	45.362	0.000	0.510	0.038	1.700
Primary focus	0.140	0.510	0.497	0.101	0.073	1.002
Affected lymph node	2.681	71.523	0.000	0.310	0.011	3.465
Necrotic degree of tumor	1.529	13.144	0.001	0.259	0.596	1.331
Complication	1.204	28.655	0.000	0.993	0.001	2.789
Classification of TCM syndromes	1.325	76.816	0.000	0.649	0.002	1.957
Karnofsky score before treatment	-1.412	72.507	0.000	-0.832	0.002	0.546
Hemoglobin	-2.373	60.167	0.000	-0.509	0.352	0.763
Serum calcium	2.813	28.573	0.000	0.059	0.897	1.124
Lactic dehydrogenase	1.802	49.876	0.000	10102	0.003	3.273
Carcinoembryonic antigen	3.561	61.549	0.000	1.359	0.031	4.873
CA199	4.812	48.237	0.000	3.201	0.001	23.412
Treatment	-0.239	4.357	0.039	-0.812	0.000	0.538
Total cumulative score after treatment	-1.321	27.967	0.000	-0.896	0.021	0.413
Effectiveness after treatment	-1.237	12.249	0.000	-0.081	0.857	0.951
Stability after treatment	-2.798	73.582	0.000	-1.987	0.022	0.130
CD_3+	-0.689	11.601	0.001	-1.131	0.018	0.357
CD4+	-0.597	9.001	0.004	0.537	0.221	1.703
CD8+	0.837	14.989	0.000	0.329	0.452	1.436
CD4+/ CD8+	-1.014	19.370	0.000	-0.026	0.889	1.001

Note: TCM: Traditional Chinese Medicine.

therapy to a certain extent. The addition of tonifying drugs into the prescription can increase the resistance ability of the patient and improve protective factors to increase survival time and quality of life.[18] TCM syndrome differentiation therapy combined with chemotherapy has a definite therapeutic effect on middle-late stage NSCLC, which is a clinically relative conclusion. In the present study, according to the treatment methods and drugs selected in clinical treatment and studies, the effects of treatment course on protective factors and risk factors were enhanced. This promoted the rehabilitation of the patient and reduced the danger of treatment by increasing the effects of protective factors, and decreasing the effects of risk factors.

In summary, compared with Western Medicine, integrated Chinese-western treatment for middle-late stage NSCLC has the advantages of a higher survival rate in middle-late stage cancer and a positive influence on prognostic factors. Our study provides a source of information for therapy selection and further research on clinical treatment methods.

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