Clinical Study on Effect of Shenlong Oral Liquid Combined with Radiotherapy in Treating Nasopharyngeal Carcinoma*

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ABSTRACT
Objective: To observe the effect of Shenlong Oral Liquid (SLOL) combined with radiotherapy in treating nasopharyngeal carcinoma (NPC).

Methods: Effects of the combined therapy, including clinical effects, changes of cellular immunity and side effects, in treating 60 NPC patients (in the treated group) were observed and compared with those of the other 60 patients treated with radiotherapy alone (in the control group).

Results: (1) The side effects of radiation in the treated group were lower than those in the control group significantly (P<0.05). (2) The short-term remission rate of nasopharyngeal and neck metastatic tumor in the two groups was not significantly different (P>0.05). (3) The dose for complete remission of nasopharyngeal and neck tumor in the treated group was lower than that in the control group (P<0.01). (4) No change of T-lymphocyte subsets was found in the treated group after treatment, but in the control group, OKT3, OKT4, and OKT4/OKT8 ratio were markedly decreased (P<0.05). (5) The survival rate in the treated group was higher than that in the control group, but with no statistical significance (P=0.0518).

Conclusion: The combined therapy of NPC with SLOL and radiotherapy is able to reduce side-effect of radiotherapy, improve the cellular immunity, reduce the dose of radiation for tumor re- mission and enhance the therapeutic effect of radiotherapy. It showed a trend of raising the long-term survival rate of NPC patients.

Key Words: nasopharyngeal carcinoma, radiotherapy, Chinese herbal medicine, T-lymphocyte subsets

Radiotherapy is the first choice of treatment of nasopharyngeal carcinoma (NPC), however, no satisfactory therapeutic effects of radiotherapy have been gotten till now. Furthermore, radiotherapy often produces a lot of side-effects, and also impairs the immune function of human body. In order to reduce side-effects of radiotherapy, and further enhance therapeutic effects of radiotherapy, 60 patients with NPC were treated with Shenlong Oral Liquid (SLOL) combined with radiotherapy, and side-effects of radiotherapy, cellular immune function and clinical therapeutic effects in patients were observed.

METHODS

Clinical Materials

All the 120 patients were inpatients hospitalized from Dec. 1996 to Dec. 1998, their diagnosis was confirmed by pathological examination, the clinical stage of the disease was assigned according to the standard formulated at the National Conference of Nasopharyngeal Carcinoma, 1992(1). According to different clinical staging, the patients were randomly divided into two groups, Group A and B. Patients in Group A (n=60) were treated by the combination of radiotherapy with SLOL, among whom there were 36 males and 24 females, aged 20-60 years, 44 years on average, 14 in stage I, 30 in stage III, and 16 in stage IV. Patients in Group B (n=60) were treated with radiotherapy alone, among whom there were 34 males and 26 females, aged 21-60 years, 46 years on average, 12 in stage II, 30 in stage III, and 16 in stage IV. The two groups were comparable in sex, age, and

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clinical staging.

Methods of Treatment
All the patients in the two groups had received radiotherapy. Nasopharyngeal tumor was treated with routine faciocervical field radiation first, 2 Gy per time, once daily, 5 times a week until the total dose of radiation was accumulated to 36 Gy, and then radiation was applied on two fields, the upper one was the preauricular field, on which radiation was applied continuously with the total dose approaching 70 Gy in 35 times within 49 days, the other field on the neck was applied with the total dose approaching 60—70 Gy in 30—35 times within 42—49 days. The source of radiation was 8-MeV X-rays or 60 Co, and 8—12 MeV electron beam was applied on neck field. To some of the patients (10 in the treated group and 8 in the control group), radiotherapy was started directly on the preauricular field.

From the first day of radiotherapy, SL-OL was given orally 20 ml per time, three times daily for the patients in Group A, 2 months as a therapeutic course. SLOL consisted of the following herbs: Radix Astragali 20 g, Fructus Ligustri Lucidi 15 g, Rhizoma Ligustici Wallichii 10 g, Radix Pseudostellariae 15 g, Radix Salviae Miltiorrhizae 20 g, Folium Sarcandra Glabra 10 g, Peretima 20 g, Radix Ophiopogonis 15 g, Herba Scutellariae Barbatae 15 g, Herba Hedyotis 15 g, Semen Coicis 15 g, and Rhubarb 6 g, it was produced by the Pharmaceutical Factory of Guangxi Medical University made into oral liquid with 3.25 g crude herbs in 1 ml.

Items of Observation
The following items were observed: (1) Acute toxic and side-effect of treatment was estimated weekly by observing body weight, mental condition and appetite, etc., and peripheral blood picture every 1—2 weeks; (2) The condition of tumor remission, both the primary tumor in nasopharyngeal region and the metastatic tumor in the neck region, were examined every week; (3) The indexes of cellular immune functions were measured before and after treatment. All patients were followed-up for more than one year.

Statistical Analysis
Radiation dose for tumor complete remission (abbreviated as tumor CR dose) and the index of cellular immune function were expressed by $\bar{x} \pm s$; $t$-test was adopted to test the significance of difference and $t^*$-test was used when heterogeneity was at variance. Chi-square($\chi^2$) test was used to compare the rates. Survival rates were calculated by life span table method; the Logrank test was used to make significance test. The analysis was completed by using PEMS 2.1 (Package Encyclopaedia of Medical Statistics) statistical software.

RESULTS

Comparison of Acute Toxic and Side-Effects
Appetite, mental condition and body weight were improved in 19 patients in Group A, accounting for 31.67% (19/60 cases); and the patients with decreased hemoglobin (Hb), platelets, and WBC in Group A only accounted for 5% (3/60 cases); while the corresponding number in Group B was 13.33% (8/60 cases) and 18.3% (11/60 cases) respectively. By $\chi^2$ test, the acute toxic and side-effect reactions in Group A was significantly less than those in the control group ($\chi^2 = 4.87$ and 3.96, $P<0.05$).

Comparison of Tumor Remission Rates
For patients in Group A, tumor remission rate of primary focus was 91.67% (55/60 cases), and that of neck metastatic tumor was 95.83% (46/48 cases); while in Group B, the corresponding number was 88.33% (53/60 cases) and 83.67% (41/49 cases) respectively. There was no significant difference between the two groups in comparison of tumor remission rate of nasopharyngeal primary focus and neck metastatic tumor ($\chi^2 = 0.09$ and 2.67, $P>0.05$).