Clinical observation on Kanglaite Injection combined with chemotherapy in the treatment of metastatic breast cancer

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We employed Kanglaite Injection (KLT) combined with NP scheme in treating 21 cases with recurrent metastatic breast cancer and obtained satisfactory results as follows.

1. Clinical data
41 cases of recurrent metastatic patients following surgery, radiotherapy or chemotherapy and confirmed by cytological, pathological and imaging examinations to have measurable lesions associated with recurrence and metastasis of advanced breast cancer. All of 41 cases were women, aged 36 to 63 years old with average age of 48 years old. Pathologically, infiltrative ductal carcinoma 21 cases, simple carcinoma 16 cases, hard carcinoma 2 cases and myeloid carcinoma 2 cases. All of them had more than one metastatic lesion. Main sites of metastasis were lung, liver, bone, supraclavicular lymph nodes and chest wall soft tissue. All of them had not received anti-cancer therapy within the last three months. Physical performance: Karnofsky score ≥ 60 points, blood, liver, kidney function and ECG were basically normal without contraindications for chemotherapy. The 41 cases were randomly divided into two groups with observation group of 21 cases and control group of 20 cases.

2. Method of treatment
Subclavian vein puncture with indwelling venous catheter was performed in all 41 cases. The observation group was treated with KLT 200ml, iv. drip for 14 consecutive days; Vinorelbine (product of Jiangsu Stockhausen Pharmaceutical Co.) 25 mg/m², dissolved into 40ml of NS, rapid i.v. drip for d1 and d8; Cisplatin 20mg/m², dissolved into 250ml of NS, i.v. drip for 5 consecutive days; The control group was treated with vinorelbine 25 mg/m², dissolved into 40ml of NS, rapid i.v. drip for d1 and d8; Cisplatin 20 mg/m² dissolved into 250ml of NS, i.v. drip for 5 consecutive days. Both groups were treated for 21 days as a cycle. Each case was treated for at least two chemotherapy cycles. The treatment group had completed a total of 77 cycles with an average of 3.67 cycles for each case. The control group had completed a total of 71 cycles with an average of 3.55 cycles in each case.

3. Method of observation
Detailed record for changes of the tumor lesions, KPS scores and body weight before and after chemotherapy was performed. During chemotherapy blood routine was checked twice per week and after chemotherapy blood routine, hepatic and renal functions, ECG, B-ultrasonograph, CT, X-ray chest film, bone scanning, etc. were checked. Statistical method adopted x² test.

4. Criteria of therapeutic effect
Evaluation was performed according to WHO’s Objective Criteria of Therapeutic Effect of Solid Tumors[1]. Complete Remission (CR), Partial Remission (PR), Stable Disease(SD), Progressive Disease(PD) and effective rate = CR+PR. The evaluation of drug’s toxicity was performed according to WHO’s Grading Criteria of Toxicity (0~IV) of Anti-cancer Drug[1]. Quality of life was evaluated according to Karnofsky scores. Increase or decrease of more than 10 points before and after treatment was evaluated as improved or deteriorated and no change as stable. The increase or decrease of more than 1kg of body weight was
evaluated as increase or decrease and less than 1kg of body weight was evaluated as stable.

5. Results

Short-term results
The observation group: CR 3 cases (14.29%), PR 12 cases (57.14%), SD 5 cases (23.81%), PD 1 case (4.76%), effective rate (CR+PR) 71.43%. The control group: CR 1 case (5.00%), PR 7 cases (35.00%), SD 10 cases (50.00%) and PD 2 cases (10.00%), effective rate (CR+PR) 40.00%. There was significant difference between the two groups (P<0.05).

Adverse reactions: Main manifestations were nausea and vomiting, leukopenia and peripheral nerve toxicity.

The observation group: nausea and vomiting (degree I-II) 7 cases, degree III-IV 0 case. Incidence of nausea & vomiting 33.33%, degree I leukopenia 5 cases, degree II 3 cases, degree III 1 case, degree IV 0 case, leukopenia rate 42.86% and degree I peripheral nerve toxicity 6 cases (28.57%).

The control group: degree (I-II) nausea and vomiting 12 cases, degree III 2 cases, degree IV 0 case, incidence of nausea and vomiting 70.00%; degree I leukopenia 8 cases, degree II 5 cases, degree III 2 cases, degree IV 1 case, leukopenia rate 80.00%; degree I peripheral nerve toxicity 5 cases (25.00%).

There were significant differences (P<0.05) in nausea & vomiting and leukopenia between the two groups, but there was no significant difference (P>0.05) in peripheral nerve toxicity. No fever, rash, phlebitis or heart, liver and kidney toxicity and no chemotherapy-related death.

Quality of life:
The observation group: improved 12 cases, stable 6 cases, declined 3 cases with improved rate of 57.14% while in the control group: improved 5 cases, stable 7 cases, decreased 8 cases, improved rate 25.00%. There was significant difference between the two groups (P<0.05).

Changes of body weight: The observation group: increased 12 cases, stable 8 cases, decreased 1 case, increasing rate 57.14%; The control group: increased 5 cases, stable 8 cases, decreased 7 cases, increasing rate 25.00%. There was significant difference between the two groups (P<0.05).

6. Discussion

Kanglaite Injection is a new effective dual-functional anti-cancer drug prepared from a TCM herb-*semen coicis*. It has prominent tumor inhibitory effect in treating a variety of tumors. The mechanism of its actions is to block cancer cells at G/M phase, up-regulate P53 gene expression and down-regulate bcl-2 gene expression thus inducing apoptosis of cells, inhibition of tumor's angiogenesis, down-regulating MUC1 gene and protein expression of MCF7 cells thus controlling tumor's growth\(^2,3\) and metastasis\(^4\). In addition it significantly reverses multi-drug resistance (MDR) of tumor cells\(^5\) and regulates levels of cytokines, improves appetite and promotes weight gain to certain degrees thus raising KPS scores and fighting against cachexia\(^6\). At the same time it can markedly improve body immune function and reduce adverse reactions caused by radiotherapy or chemotherapy.

The treatment of advanced breast cancer is mainly relying on combination chemotherapy. To some Patients who failed in the first-line chemotherapy the drug vinorelbine (NVB) has a good therapeutic effect.
The mechanism of its actions is mainly the suppression of Tubulin polymerization and the formation of microtubule and depolymerization of microtubule so that proliferation of tumor cells is stopped at the phase of mid-mitosis. Therefore the drug can be grouped into cell cycle specific drug.

Kanglaite Injection combined with NP chemotherapy scheme in the treatment of metastatic breast cancer has a synergistic effect and can reduce adverse reactions of chemotherapy. At the same time it can also improve patient’s quality of life, increase body weight without notable toxic and side effects.

[References]