Clinical observance on Kanglaite Injection (KLT) combining with concurrent radio- and chemo-therapy in treating local recurrence of post-operative rectal cancer

Qi Zengping, Wang Yuqiang, Cheng Huijuan, Zhang Qiuxia

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Application of concurrent radio- and chemo-therapy is one of the major ways for treating local recurrence of post-operative rectal cancer patients. In order to improve the effectiveness of concurrent radio- and chemo-therapy, clinical study was performed for local recurrence of post-operative rectal cancer patients and compared between patients applying concurrent radio- and chemo-therapy with KLT and without KLT among 62 cases from Jan. 2007 to Mar. 2009. The result of report is as follows:

1. Information and method
1.1 General information
The age of 62 cases is from 42 to 78 and the median age is 59, all of them are defined as local recurrence of post-operative rectal cancer (LRRC). Among 62 cases, 20 cases performed radio- and chemo-therapy, 25 cases did chemotherapy, 8 cases took radiotherapy and 9 cases were without any treatment. 6-38 months left from post operation to recurrence and metastasis. 23 cases are anastomotic recurrence and 29 cases of recurrence are on Pelvic wall or in front of rumpbone. All of diagnoses of patient are proved through type-B ultrasonic, CT and MRI test. 20 cases are adenocarcinoma metastatic, which has pathology basis. 62 cases didn’t take radio- or chemo-therapy after recurrence and the duration after operation exceeds 12 months. KPS ≥ 70, estimated survival time ≥ 6 months and no radio- and chemotherapy contradiction. Divide into treatment group (32 cases) and control group (30 cases) randomly and the general information is almost equal.

1.2 Treatment regimen
Treatment group: Apply three-dimensional conformal radiotherapy technology (3DCRT) DT55-60 Gy, 1.8-2.0Gy/time, 5f/week. Chemotherapy treatment: Oxaliplatin, 100mg/m², i.v., d1; calcium folinate, 200 mg/m², i.v., d1-d2; 5-fluorouracil, 2.0 mg/m², last for 48-72 hrs, 21 days are a cycle, four cycles. Take radio- and chemotherapy while applying KLT, which is 200ml/d, i.v., a cycle includes 21 days and start the 2nd cycle 7 days after the 1st cycle, altogether 2 cycles. Control group: concurrent radio- and chemotherapy alone and the way for radio- and chemotherapy is the same.
1.3 Evaluation on effectiveness and adverse reaction
Four weeks after treatment, check pelvic cavity for short-term effectiveness through B type ultrasonic, CT and MRI. According to Response Evaluation Criteria in Solid Tumors (RECIST) identified by WHO, it covers CR: all of focuses are disappeared, PR: the focus decreases by more than 50%; SD: the focus decreases by less than 50% or increases by less than 25%; PD: the focus increases by more than 25% or new focus is appeared. The effective rate is CR+PR and the reverse reaction is estimated according to WHO anti-cancer drug adverse reaction standard. The toxicity reaction of hematological system manifested by leucoctye: grade 0 ≥ 4.0 × 10^9/L, grade I: (3.0-3.9) × 10^9/L, grade II: (2.0-2.9) × 10^9/L, grade III: (1.0-1.9) × 10^9/L, grade IV < 1.0 × 10^9/L.

1.4 Statistic analysis
Apply SPSS 11.0 statistical software and x^2 for enumeration data, P < 0.05 stands for difference, which has statistic significance.

2. Result
2.1 Short-term effectiveness
Treatment group: 8 cases of CR, 20 cases of PR and the total effective rate are 87.5%. Control group: 5 cases of CR, 15 cases of PR and the total effective rate are 66.67%. The difference between those two groups in total effective rate has statistical significance.

2.2 Survival rate
1 and 2 years of survival rate in treatment group account for 87% and 56% respectively and 65% and 51% for control group. The difference between those two groups in 1 year of survival rate has statistical significance (P < 0.05).

2.3 Adverse reaction
The decrease rate of leucocyte in treatment group is 46.88% (15 cases), of which 12 cases of I-II class of leucocyte decreased, 3 cases of III-IV class of leucocyte decreased. The decrease rate of leucocyte in control group is 73.33% (22 cases), of which 14 cases of I-II class of leucocyte and 8 cases of III-IV class of leucocyte decreased.

3. Discussion
As the view of 2cm above insection in resection operation for treating rectal cancer is accepted by people and anastomat improves and promotes in recent decade, the sphincter-preserving surgery is widely used. However, the No. of recurrence cases clinically gets to increase.
Specifically, the local recurrence rate post-operation in stage II reaches 20%-40% and 40%-70% in stage III. The treatment for local recurrence (recurrence in anastomosis, pelvic cavity ect.) is still difficult and poor prognosis\(^1\). As radiotherapy technology improves, 3DCRT, as a palliative treatment for recurrence of post-operative rectal cancer, turns to be popular for clinical application. Oxaliplatin, as a third generation of platinum antineoplastic drug, is featured by high water-solubility, low toxicity and significant effectiveness in treating cancer, which has inhibitive impact on rectal cancer that is resistant to cis-platinum\(^2\). The new standard treatment for advanced rectal cancer is to apply oxaliplatin and 5-fluorouracil combing with chemotherapy while using calcium folinate to make it more sensitive. Zheng Dengyun et al\(^3\) apply radiotherapy while taking small-dose 5-fluorouracil combing with calcium folinate to treat local advanced and recurrence of rectal cancer, which has achieved the strengthening effect of radiotherapy. KLT is an anti-tumor compounds, extracting from coix seed – a kind of TCM. The studies in recent years confirmed that KLT can kill and greatly inhibit many kinds of cancer cells\(^5,6\). The mechanism of KLT in anti-cancer includes: (1) Play a role in cancer cells in G2/M period, inhibiting mitosis of cancer cells; (2) Induce apoptosis of cancer cells; (3) Impacting gene expression of cancer cells; (4) Inhibiting angiogenesis; (5) Fighting against cachexia; (6) Reversing MDR\(^7\). The result of the group using KLT combing with concurrent radio- and chemotherapy is as follows: the short-term effective rate is 87.5%, 1 year of survival rate is 87%, decrease rate of leucocyte is 47; while the short-term effective rate of the group using concurrent radio- and chemotherapy alone is 66.67%, 1 year of survival rate is 65% and decrease rate of leucocyte is 73.33%. The application of KLT combing with concurrent radio- and chemotherapy can improve clinical symptoms and quality of life, extend survival period and protect function of marrow, indicating that taking KLT combing with concurrent radio- and chemotherapy in treating rectal cancer can strengthen effectiveness while reduce toxicity.

Reference


