Clinical Observation of the Dispelling Turbid Qi and Stopping Nausea and Vomit Decoction in Prevention of Nausea and Vomiting in Chemotherapy with Cisplatin

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Abstract

Objective: To observe the efficacy and safety of dispelling turbid qi and stopping nausea and vomit decoction in the prevention of nausea and vomiting in the chemotherapy with cisplatin programs.

Methods: 60 patients with tumors in the chemotherapy with cisplatin programs who were randomly selected into the experimental group (patients were treated with the dispelling turbid qi and stopping nausea and vomit decoction) and the control group (patients were treated with Ondansetron) which had 30 patients in each group. The control group was treated with Ondansetron injection, while the experimental group was treated with the dispelling turbid qi and stopping nausea and vomit decoction and Ondansetron. The efficacy of the treatment on the two groups of patients with nausea and the quality of survival was observed, and the number of the white blood cells and platelets in the peripheral blood of the patients in both groups was counted to observe the effects on their immune system.

Results: The number and extent of the reduction of white blood cells and platelets in the treatment group were significantly lower than those of the control group, and there were significant differences before the treatment and after treatment. However, the corresponding indicators in the control group were significantly reduced. The overall efficiency of the treatment group is 90%, while the overall effectiveness of the control group. The differences are statistically significant (P<0.05). The KPS scores of the treatment group also significantly increased, with the differences between the two groups statistically significant (P<0.05).

Conclusion: The dispelling turbid qi and stopping nausea and vomit decoction is better in the treatment of nausea and vomiting caused by chemotherapy with cisplatin, is easy to use and safe and worth clinically promoting.

Keywords: the dispelling turbid qi and stopping nausea and vomit decoction; Chemotherapy; Nausea; Vomiting

1. Introduction

Patients with tumors often experience varying degrees of nausea and vomiting during chemotherapy or after chemotherapy, which is the

most common adverse reaction of chemotherapy^[1]. Chemotherapy -induced nausea and ventilation, CINV, is a more painful reaction in chemotherapy, which causes patients' eating disorders, malnourishment, dehydration and psychological problems, which seriously affect patients' quality of life. Patients become resistant to chemotherapy, and even stop chemotherapy, so their conditions become worse. This is mainly due to the fact that chemotherapy stimulates the chemoreceptor trigger zone in the cranial system.

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In recent years, cancer incidence and mortality have increased year by year. Nausea and vomiting symptoms after chemotherapy have seriously affected patients' quality of life. They have attracted attention from all medical professionals, and have deepened their research in this field.

Studies show that CINV is more likely to occur in patients in the chemotherapy with cisplatin programs and that CINV is positively associated with chemotherapy cycles^[2]. Overseas researchers found that CINV was more risky in patients who did not follow clinical antiemetic guidelines to take antiemetic drugs. Currently, 5-HT3 receptor blockers are the most widely used drugs in clinical treatment such as Ondansetron, Tropisetron, and Granisetron, which are more efficient in the treatment of acute CINV but are less effective in the treatment of delayed vomiting. Research found that acute CINV was associated with 5-HT3, while delayed CINV was associated with P substances. The NK-1 receptor blocker can reduce the affinity of the P-1 substance and NK-1, thereby reducing symptoms such as nausea, vomiting, etc. Currently, NK-1 receptor blockers include Netupitant, Rolapitant, Aprepitant and so on.

In recent years, traditional Chinese medicine has been given priority to nausea and vomiting after chemotherapy. Traditional Chinese medicine has a unique advantage in the treatment of CINV: emphasizing the syndrome differentiation and treatment and flexibility in the treatment of CINV. The treatment methods are numerous such as traditional Chinese medicine which is orally taken and externally applied, acupuncture, and point application, which are very easy to operate, and cheap and have fewer adverse reactions, so patients easily accept the methods. The dispelling turbid qi and stopping nausea and vomit decoction is derived from the "Guizhi Tang" method which ranks first in the Treatise on Febrile Diseases. After the innovative development by Professor Lu Chonghan and his pupils Dr. Liu Lihong and Dr. Tang Nong, the dispelling turbid qi and stopping nausea and vomit decoction was formed by the prescriptions wrecking the pathogen and supporting the vital qi. This experiment was designed to provide new methods and ideas for clinical treatment observing efficacy and safety of the dispelling turbid qi and stopping nausea and vomit decoction against nausea and vomiting in the chemotherapy with cisplatin programs.

2. Materials and methods 2.1 General data

60 cases of patients with tumor in the chemotherapy with cisplatin programs in our hospital from July 2019 to May 2020 were selected as the research object, and they were divided into two groups randomly. 30 cases in the control group; 30 cases in the observation group. The differences between two sets of relevant impact factors are not statistically significant (P>0.05).

2.2 Diagnostic Criteria

The detection of x-line, Ultrasound, CT, cytological techniques, histopathology and so on confirm the presence of malignant tumors.

2.3 Inclusion criteria

Patients with malignant tumors who undergo chemotherapy with platinum are also eligible for (1) aged between 18 and 65; (2) no digestive channel obstruction;(3) intracranial hypertension such as no brain transfer;(4) no gastrointestinal complications such as nausea and vomiting in 24h before chemotherapy;(5) the function of the liver and the kidney is normal and they can undergo two-cycle all-round chemotherapy;(6) the compliance is good.

2.4 Excluding criteria

Any person who does not meet criteria for inclusion.

2.5 Research methodology

The 60 patients who met the criteria were randomly classified into the treatment group (traditional Chinese medicine) and the control group (Ondansetron). The treatment group uses the dispelling turbid gi and stopping nausea and vomit decoction which is composed of 15 grams of ramulus cinnamomi, 10 grams of angelica dahurica, 15 grams of rhizoma acori tatarinowii, 15 grams of oroxylum indicum, 15 grams of atractylodes lancea, 30 grams of atractylodes macrocephala koidz, 30 grams of poria cocos, 15 grams of almond protein, 15 grams of amomum villosum, 15 grams of rhizoma Pinelliae Praeparatum, 15 grams of ginger, 10 grams of orange peel, 5 grams of roasted liquorice decoction, 15 grams of caulis bambusae, 15 grams of white peony root if patients are stomachache, 10 grams of fructus aurantii, 10 grams of angelica if patients suffer constipation, and 10 grams of rhubarb. The boil-free traditional Chinese medicine (produced by PuraPharm Corporation) was dissolved with 400 millilitres boiling water per day and placed to 40 degrees Celsius, and patients 200 millilitres per day before

morning and dinner. The number of days of the drug supply is consistent with the number of days of the corresponding chemotherapy. The number of days of the drug supply by the controlled group (Ondansetron) is consistent with the number of days of the corresponding chemotherapy. 8 grams of Ondansetron (produced by Qilu Co., Ltd.) were injected with intravenous treatment on chemotherapy days, 30 min before chemotherapy and 8h after chemotherapy.

All 60 patients with tumors included in the study received a two-cycle all-round chemotherapy. Both groups were normally treated before chemotherapy with 8 grams of injection and 10 grams of intravenous injection, both of which were once per day from the first day of chemotherapy to the last day of chemotherapy. The treatment group added the dispelling turbid qi and stopping nausea and vomit decoction. The number of the white blood cells and platelets in the peripheral blood of the patients in both groups was counted.

2.6 Observation indicators

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The adverse reaction of the digestive system such as nausea and vomiting during chemotherapy and changes in the quality of life of the patients were observed, and the adverse reaction was observed to terminate the test in time or exclude the tested patient.

2.7 Therapy Standard

Negative reaction of digestive systems such as nausea and vomiting were rated according to World Health Organization (WTO) evaluation indicators^[4]. Level 0: No nausea and vomit; Level Level I: nausea (light), no vomiting; Level II: nausea (light), no more than two vomits within 24h without affecting daily life and diet; Level III: nausea (moderate), 3 to 5 vomits within 24h, affecting daily life and diet; Level IV: nausea (heavy), over 5 vomits within 24h, and

large amounts of digestive fluids are lost and patients need to rest by lying in bed. The negative reaction of the digestive system such as nausea and vomiting in patients were observed in 24h with level 0 and level 1 as valid; level 2 as effective; and level 3 and 4 as invalid.

The World Health Organization (WTO) evaluation indicators are used to rate nausea, vomit and diet: IV class: nausea (heavy), vomiting more than five times within 24 h, and a large amount of digestive fluid is lost and patients need to rest in bed. Patients treated within 24h with the level of nausea, vomit and the negative reaction of the digestive system are shown by level 0 and level 1 labeled as valid, level 2 as effective, and level 3 and 4 as invalid. Quality of life is assessed by the Kamofsky, KPS, and is used to refer to changes in the score. This study uses SPSS 18.0 to analyze the data, the measurement data is tested by the X2 test, the measurement data is used by the t-test, the grade data is used by the rank sum test, and P<0.05 is statistically significant to test difference.

2.8 Statistical method

This study uses SPSS 18.0 to analyze the data, the measurement data is tested by the X2 test, the measurement data is used by the t-test, the grade data is used by the rank sum test, and P<0.05 is statistically significant to test difference.

3. Results

The number and extent of the reduction of white blood cells and platelets in the treatment group were significantly lower than those of the control group, and there were significant differences before the treatment and after treatment. However, the corresponding indicators in the control group were significantly reduced. As shown in table 1.

Table 1. The change of white blood cells and platelets before and after treatment

(n=30 x±s)							
White blo	ood cells	Platelets (×10/L)					
Before treatment	after treatment	before treatment	after treatment				
5.24±0.83	4.16±0.47	155.0±31.7	146. 9± 22. 9				
5.12±0.09	3.17±0.75	154.2±40.3	101. 7 \pm 14. 6 [*]				
	Before treatment 5.24±0.83	White blood cells Before treatment after treatment 5.24±0.83 4.16±0.47	White blood cellsPlateletsBefore treatmentafter treatmentbefore treatment5.24±0.834.16±0.47155.0±31.7				

^aP<0.01in comparison with before treatment

The overall efficacies of treatment and control groups were compared, the overall efficiency of the treatment group was 90%, significantly better than

the overall efficiency of the group which was 72.3%, and the two were statistically significant (^aP <0.05). As shown in table 2. 1494

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Table 2. efficacy comparison

groups	cases	valid	effective	invalid	overall efficacy/%
The treatment group	30	23	4	3	90 ^a
The control group	30	20	2	8	73.3

Comparing the two groups' KPC scores before and after treatment shows no significant change in the KPC score before treatment in the two groups, both of which are not statistically significant (P>0.05); the difference in the KPC score in the two groups after treatment is noticeable, and the increase of KPS scores in the treatment group compared with the controlled group is more significant (P<0.05). As shown in table 3.

Table 3 the comp	arison of KPS score	s in the two groups
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groups	cases	before treatment	after treatment
Treatment group	30	86.3±5.4ª	83.5±9.4 ^{ab}
Control group	30	82.6±7.8	73.8±8.6ª

4. Negative Reactions

Both the treatment and control groups have no adverse and allergic reactions during treatment.

5. Discussion

The incidence of malignant tumors has increased year by year due to the effects of various internal and external environmental factors. In medical terms, the cancer is malignant tumors originating in epithelial tissues and is the most common category of malignant tumors. Malignant tumors originating in the interleaf tissue are commonly referred to as sarcoma. There are a few malignant tumors that are not named according to the above principles, such as nephroblastoma and teratocarcinoma cell, etc. The term "cancer" is generally used to refer to all malignant tumors^[5]. The cancer has a complex process with many steps and many factors, with many biological characteristics such as cell differentiation and proliferation anomalies, loss of control overgrowth, wettability, and transfer. It has three processes: causing cancer, cancer promotion and cancer evolution. It is closely associated with smoking, infection, exposure, environmental pollution, unreasonable diet, and genetic factors. The causes of tumors and the pathogenic mechanism are still not sufficiently well understood, so malignant tumors have not been fully defined as yet. Studies found that malignant tumors have their own basic characteristics. As a type of disease, although the different parts of the malignant tumor occur differently, the basic characteristics of the cell abnormality exist in all cases. Modern immunology argues that the development and changes of tumors are closely associated with the immune system. If the function of the organism is gradually reduced with the constant effects on certain tumor

factors, it gives the tumor cell the opportunity to develop. But if the function of the organism is enhanced, it can inhibit the continued growth of the tumor cell and even eliminate the tumor cell. Thus, clinical treatment of malignant tumors is expected to lead to fundamental treatment only if the immune capacity of the organism is constantly improving^[6].

The traditional Chinese medicine has classified malignant tumors as accumulation and found it to be caused by the accumulated intoxication. Chemotherapy is an important treatment for malignant tumors, but chemotherapy also makes patients suffer a lot of severe pain and often suffer from a number of noticeable, persistent and unbearable complications. Nausea and vomiting are the main side effects of chemotherapy. There are three reasons of nausea and vomiting caused by chemotherapy drugs: first, the chemoreceptor trigger zone is closer to the vascular angiology, and chemotherapy drugs or toxic products in the vessels more susceptible to stimulating the are chemoreceptor trigger zone and send stimulation signals to the vomiting central center; second, chemotherapy drugs can stimulate the gastrointestinal contiguous membrane to release neurotransmitters from Vagus nerve and sympathetic nerve to the central vomiting, and combine with corresponding receptors, causing vomiting; third, some mental sensory factors directly stimulate the brain pathway to cause vomiting and this is more visible in reflex vomiting. Chemotherapy causes vomiting in three categories: acute vomiting, delayed vomiting, and anticipatory vomiting. Acute vomiting occurs within 24 hours of chemotherapy but is often the most severe vomiting. Delayed vomiting is mostly within 5 to 7 days after chemotherapy. It tends to be more acute,

and less intensive, and tends to last a long period and affect the quality of life. Anticipatory vomiting is mainly conditioned, that is, patients vomit during the first chemotherapy, and vomiting occurs before the next chemotherapy^[7].

In recent years, significant progress has been made in research on the prevention and treatment of tumors, and the study of postchemotherapy nausea and vomiting has been increasingly valued. Active and effective prevention and treatment of vomiting caused by chemotherapy is important for improving the quality of life of tumor patients. The most effective way to control nausea is to use the antiemetic drugs and there are many types of antiemetic drugs: such as phenothiazine (such as Phenergan and Diphenhydramine), dopamine receptor antagonists (such as metoclopramide), antihistamine and so on. The derivatives of 5hydroxychromatine 3 receptor antagonists are used in clinical use and are the preferred drug for nausea and vomiting treatment after chemotherapy. Since cytotoxic chemotherapy can hurt gastrointestinal mucous membrane, in particular the ileocolic membrane, the latter releases 5hydroxytryptamine in the enterochromaffin cells, uses 5-HT3 receptors in the vagus nerves or chemoreceptors to transmit neurotransmitters and thus stimulates the vomiting center to cause people to vomit. 5-HT3 receptor antagonists prevent 5hydroxytryptamine released from the membrane gastrointestinal mucous from combining with 5-HT3 receptors and thus vomiting was inhibited ^[8]. The most common adverse reactions of such drugs include headaches, constipation, diarrhea, and mild elevated transaminase, which may also lead to illusions and increased blood pressure in patients ^[9].

The trends of research on the reduction of nausea and vomiting side reaction in the chemotherapy are (1) to study in-depth the peripheral and central mechanisms of nausea and vomiting in the chemotherapy, especially the mechanisms of delayed vomiting. (2) to conduct animal experiments with Chinese and Western drugs which can be effective in dispelling nausea and vomiting, and to explore intrinsic mechanisms of preventing nausea and vomiting in the chemotherapy from a modern pharmacological perspective, such as effects on immune indicators, gastrointestinal hormones, peripheral and central neurotransmitters, neurotransmitters, and receptors of the nervous system. (3) To conduct strict clinical design and perform required laboratory examinations to scientifically confirm

the effects of the drugs. (4) to develop Western drugs that are more safe, cheaper and more effective in delayed vomiting. (5) to develop highly effective and highly specific Chinese pharmaceutical products, especially Chinese medicine which should make most of advantages and avoid disadvantages, find a position on delayed vomiting, and move ahead as soon as possible in the forefront of the times. A large number of clinical studies suggest that the traditional Chinese medicine can make patients after chemotherapy feel sick. The intervention of nausea and vomiting can effectively alleviate the clinical symptoms of patients, slow the development of tumors, and improve the quality of their survival.

Vomiting, a sign of clinical characteristics, caused by stomach failure and irregularities and adverse rising of stomach qi, are food and sputum rise from the stomach and come out of the mouth. Nausea has sound without things out of the mouth and vomiting has things out of the mouth without sound. Traditional Chinese medicine believes that the falling of the stomach qi is smooth and that if the stomach gi does not fall but rise, the clinical symptoms of nausea and vomiting will appear. The deficiency of the stomach qi is also an important reason for the stomach failure and irregularities. Patients with accumulated syndrome are initially very ill, toxins are filled in the Triple burners, vital qi and pathogen struggle fiercely, and qi moves irregularly, so nausea and vomiting appear. Western chemotherapy is cytotoxic and is also damaging to normal tissues while killing cancer cells. Traditional Chinese medicine believes that chemotherapy focuses on attacking pathogen, is cold in nature, and long-term use can hurt gi to cause malfunction of the spleen and the stomach, so nausea, anorexia and abdominal pain appear. The patients who have been treated with chemotherapy are deficient in Ben and excessive in Biao: the gi in the spleen and the kidney is deficient which is Ben, and feeling cold, sputum, toxins and blood stasis are Biao. The pathogens and toxins of chemotherapy hurt gi in the stomach and cause damage to the human body. Therefore, patients with accumulated syndrome have been hurt by a long-term chemotherapy, have deficient qi and become weak. The spleen and the stomach are hurt, so there are sputum and the complex pathogenic condition with deficiency and excess. But whether pathogens hurt the stomach, or the spleen and the stomach are weak, the basic pathogenesis is that the stomach gi cannot fall but rise. Patients with malignant tumors often suffer

from vomiting, dizziness, anorexia, abdominal pain, abdominal bloating, diarrhea or constipation. The tongue quality is light, the tongue coating is thick, and the pulse is slippery or weak. They show qi is impaired and pathogenic dampness blocks the Triple burners. This study observes the efficacy and safety of the dispelling turbid gi and stopping nausea and vomit decoction in the prevention of nausea and vomiting in the chemotherapy with cisplatin programs. The dispelling turbid qi and stopping nausea and vomit decoction is derived from the "Guizhi Tang" method which ranks first in the Treatise on Febrile Diseases. The "Guizhi Tang" is to cure nausea and vomiting and is composed of cassia twigs, peony, licorice, ginger, and fructus ziziphi jujubae and thus can produce perspiration and harmonize Ying-qi and Wei-qi. The "Guizhi Tang" can regulate meridian-QI of TAI YANG and thus make people energetic. Patients with chemotherapy for a long time lack qi in the spleen and the stomach and the vital gi is deficient. The spleen is responsible for ascending the clear, and the stomach is responsible for descending the turbid. The spleen and the stomach are the root of acquired constitution, and qi and blood are the source of life. If the spleen is weak, it cannot transport humidity, the humid pathogens are wild and block qi. Yang-qi is not allowed to rise so life lacks blood and gas. The spleen and the stomach are deficient in qi and blood and no origins are responsible for ascending the clear and descending the turbid. So, nausea and vomiting appear. Cassia twigs are the main medicine in the "Guizhi Tang". The taste is bitter, the temperature is mild, and the cassia twigs can cure cough with dyspnea, and strengthen the middle burner and benefit vital energy. Long-term use can make people energetic and improve emotions. Experimental studies show that during chemotherapy, patients with mental stress and depression are more likely to have symptoms of gastrointestinal disorders, such as nausea, abdominal pain and abdominal bloating. Therefore, maintaining positive and optimistic good mentality during chemotherapy is more conducive to preventing symptoms such as nausea and vomiting. The peony is bitter and warm in nature, responsible for pathogens and abdominal pain, blood-arthralgia, fever, hernia, pain, gas and piss. Cassia twigs and the peony work together to make the spleen and the stomach function. The dry ginger is bitter, warm in nature, and responsible for fullness sensation in chest and cough with dyspnea, can supply qi and prevent nausea and sick feeling. Licorice and jujube can palliate medicine and supply

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qi. From this point of view, the "Guizhi Tang" focuses on the Triple burners, pathogens and humidity come out of the Triple burners, and Yangqi is cared. The dispelling turbid qi and stopping nausea and vomit decoction has cassia twigs, angelica dahurica, acorus tatarinowii schott, and oroxylum indicum which work together to dispel pathogens and humidity^[11]. Atractylodes lancea, atractylodes macrocephala, poria, and amomum cardamomum which are warm in nature, can remove coldness and dampness, strengthen the spleen and the stomach, make the middle burner smooth, and connect the upper burner and the lower burner. The fructus amomi can descend gastric qi and receive qi from the kidney. The ginger makes the middle burner and the lower burner warm, eliminate coldness and stop vomiting. Cassia twigs can ascend and descend qi, so qi can enter the lower origin, so that qi can go out without hurting vital energy. The Triple burners resume their functions so that people can digest, process and evacuate normally^[12]. This medicine is not designed to stop nausea and vomiting but it can stop nausea and vomiting. It is different from other medicines which prevent nausea and vomiting from the point of the middle burner. Prior clinical observations have shown that this decoction can significantly reduce the gastrointestinal side effects of chemotherapy, relieve nausea and vomiting, anorexia, abdominal bloating, abdominal pain, diarrhea, constipation and other symptoms, and improve patients' quality of life during chemotherapy.

This experiment randomly selected 60 cases of patients with tumor in the chemotherapy with cisplatin programs in our hospital from July 2019 to May 2020 as the research object, and they were divided into two groups randomly. 30 cases in the control group; 30 cases in the observation group. All 60 patients with tumors included in the study received a two-cycle all-round chemotherapy. Both groups were normallv treated before chemotherapy with 8 grams of injection and 10 grams of intravenous injection, both of which were once per day from the first day of chemotherapy to the last day of chemotherapy. The treatment group added the dispelling turbid qi and stopping nausea and vomit decoction. The number of the white blood cells and platelets in the peripheral blood of the patients in both groups was counted.

The adverse reaction of the digestive system such as nausea and vomiting during chemotherapy and changes in the quality of life of the patients were observed, and the adverse reaction was Qinfeng Huang, Yinbiao Zhang, Lian Chen, Yin Liu, Ailing Wei, Tongbiao Wang, Zhen Rong, Zengguang Huang, Weiping Zheng, Haitao Gui

observed to terminate the test in time or exclude the tested patient. Results show that the number and extent of the reduction of white blood cells and platelets in the treatment group were significantly lower than those of the control group, and there were significant differences before the treatment and after treatment. However, the corresponding indicators in the control group were significantly reduced. This means the dispelling turbid gi and stopping nausea and vomit decoction can improve patients' immune ability to some degree. There are 23 valid cases, 4 effective cases, and 3 invalid cases in the treatment group and the overall efficiency is 90%, while there are 20 valid cases, 2 effective cases, and invalid cases in the control group, with the overall effectiveness of 72.3%. The differences are statistically significant (P<0.05). The treatment group is significantly better than the control group. The KPS scores of the treatment group also significantly increased, with the differences between the two groups statistically significant (P<0.05). Comparing the two groups' KPC scores before and after treatment shows no significant change in the KPC score before treatment in the two groups, both of which are not statistically significant (P>0.05); the difference in the KPC score in the two groups after treatment is noticeable, and the increase of KPS scores in the treatment group compared with the controlled group is more significant (P<0.05). This shows that the dispelling turbid qi and stopping nausea and vomit decoction has a significant clinical effect on the prevention of nausea and vomiting in the chemotherapy with cisplatin programs. Its antiemetic effect is obvious, and its safety is high, which can significantly improve patients' quality of life after chemotherapy. There were no adverse reactions and allergic reactions in this experiment.

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