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Article

Study on the Effect of Aprepitan on Chemotherapy-related Adverse Reactions of Gynecological Malignancies

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Abstract: Objective: To explore the clinical efficacy and safety of aprepitan in preventing chemotherapy-associated nausea and vomiting (CINV) in patients with gynecological malignancies. Methods: A total of 98 patients with gynecological malignant tumors in our hospital from January 2020 to December 2022 were selected and randomly divided into an observation group and a control group, with 49 cases in each group. The control rates of nausea and vomiting, symptom scores and adverse reactions were compared between the two groups. Results: The total score of R-INVR in the observation group was lower than that in the control group, the remission rate of nausea and vomiting and the total score of FLIE were higher than those in the control group ($p < 0.001$), and the incidences of adverse reactions such as fatigue, constipation, headache, diarrhea and anorexia were all lower than those in the control group ($p < 0.05$). Conclusion: Aprepitan can relieve nausea and vomiting caused by chemotherapy in patients with gynecological malignant tumors, and it has good safety. It is suitable for antiemetic management during chemotherapy in gynecological malignant tumors.

Keywords: arepitan; Chemotherapy for gynecological malignancies; adverse reactions

1. Introduction

Cancer treatment-induced nausea and vomiting (CTNV) refers to the common adverse reactions in cancer patients during the treatment process. It covers chemotherapy-related nausea and vomiting (CINV), radiotherapy-related nausea and vomiting (RINV), and nausea and vomiting caused by tumor resection surgery (PONV). Among these three types of adverse reactions, CINV and RINV can seriously interfere with the daily diet and sleep of cancer patients, reduce their quality of life, or cause them to interrupt the anti-tumor treatment plan due to their inability to tolerate it, thereby affecting the treatment effect. As early as 2016, the Chinese Society of Clinical Oncology (CSCO) launched the “CINV Standardized Management Project”, providing professional guidance for the prevention and control management of CINV in clinical practice. Since then, more and more hospitals in China have successively established “no-vomiting wards”, building an integrated management system where doctors, nurses and patients closely collaborate. Gynecological malignancies such as cervical cancer, endometrial cancer and ovarian cancer seriously threaten women’s physical health and life safety. At present, the main clinical treatments are surgery and radiotherapy, but they are prone to cause side effects such as nausea and vomiting. Aprepitan, as a highly selective NK-1 receptor antagonist, has a very good effect in preventing acute and delayed nausea and vomiting caused by multi-cycle chemotherapy with a high risk of vomiting. However, its exact effect on patients with gynecological malignancies still needs to be further explored.

2. Materials and Methods

2.1. General Data

A total of 98 patients with gynecological malignant tumors admitted from January 2020 to December 2022 were included as the research subjects and all received platinum-based concurrent chemoradiotherapy. They were randomly divided into the observation group and the control group, with 49 cases in each group. The age of the observation group ranged from 31.50 to 75.20 years old, with an average age of (53.27 ± 11.46) years old. The body mass index (BMI) ranged from 17.84 to 28.93 kg/m^2, with an average of (22.15 ± 3.27) kg/m^2. The disease types included 26 cases of cervical cancer, 14 cases of ovarian cancer, and 9 cases of endometrial cancer. According to the staging criteria of the International Federation of Obstetricians and Gynecologists (FIGO), they covered 8 cases in stage IB, 18 cases in stage II, 19 cases in stage III, and 4 cases in stage IV. The age of the control group ranged from 33.10 years to 76.80 years, with an average of (54.83 ± 10.92) years. The body mass index ranged from 18.02 to 29.17 kg/m^3, with an average of (21.78 ± 3.56) kg/m^2. The distribution of disease types was 27 cases of cervical cancer, 13 cases of ovarian cancer, and 9 cases of endometrial cancer, among which there were 7 cases in stage IB, 17 cases in stage II, 20 cases in stage III, and 5 cases in stage IV. After examination, there was no statistically significant difference in the baseline data between the two groups of patients ($p > 0.05$), and they were comparable.

Inclusion criteria: (1) According to the "Chinese Expert Consensus on Multidisciplinary Diagnosis and Treatment of Gynecological Malignancies (2022 Edition)", cervical cancer, ovarian cancer or endometrial cancer has been confirmed by hipathological histology, and the FIGO stage is IB to IV. (2) Aged 30 to 75, female. (3) The patient received platinum-based concurrent chemoradiotherapy for the first time, and the risk level of vomiting caused by the chemotherapy regimen was assessed as medium-high. (4) No systemic anti-tumor treatment had been received before enrollment. (5) The functions of the heart, liver and kidneys are basically normal. The expected survival time is no less than six months.

Exclusion criteria: (1) A history of chronic nausea and vomiting or vestibular dysfunction. (2) Any antiemetic drugs have been used within 24 h before enrollment. (3) Combined with intestinal obstruction, brain metastasis or other organic diseases that may cause nausea and vomiting. (4) Allergic to apirpitan or other NK-1 receptor antagonists. (5) Pregnant or lactating women. (6) Suffering from severe mental illness or cognitive dysfunction and unable to cooperate with the assessment.

2.2. Intervention Methods

Both groups received chemotherapy treatment with moderate to high risk of vomiting. The chemotherapy drugs included cisplatin (dose 75 mg/m^2, repeated every 3 weeks), carboplatin (AUC 5-6, repeated every 3 weeks), or docetaxel (75 mg/m^2, combined with carboplatin). All chemotherapy was administered intravenously, and hydration and electrolyte supplementation were routinely performed before treatment. The control group was intravenously given a single injection of palonosetron 0.25 mg 30 min before chemotherapy, combined with intravenous injection of dexamethasone 12 mg (on the first day), and then orally administered dexamethasone 8 mg daily from the second to the fourth day. Omeprazole 40 mg was administered intravenously once daily to prevent gastrointestinal reactions. During chemotherapy, patients are required to eat small meals frequently, avoid greasy and irritating foods, and mainly consume light, easily digestible semi-liquid or soft foods. It is encouraged to have 5 to 6 meals a day. Each meal should not be too full. It is also recommended to drink water or clear soup between meals. The daily fluid intake should be no less than 2000 mL. Consuming an appropriate amount of ginger products or soda crackers and other foods that can help relieve nausea. If the patient experiences vomiting, they should fast for a short period of 2 to 4 h. Once the symptoms ease, try liquid foods such as plain water, thin porridge or lotus root starch, and then gradually resume eating. First. For those who do not consume enough, oral nutritional supplements (Ansu, Nengquanli) should be given, with an additional daily intake of 200 to 400 kilocalories. If the oral energy intake is less than 60% of the required amount for three consecutive days, enteral nutrition support should be considered. In terms of non-pharmaceutical management, patients are guided to maintain oral hygiene, rinse their mouths with normal saline several times a day, keep the ward environment well-ventilated and odor-free, and it is recommended that they remain in a sitting or semi-reclining position for at least one hour after meals. When experiencing mild nausea, one can use methods such as listening to music and relaxation exercises to divert attention. All patients discharged after chemotherapy received daily symptom telephone follow-up. The frequency and severity of nausea and vomiting were recorded for five consecutive days, and they were guided to record daily intake and output as well as dietary conditions. Instruct the patient to return to the hospital immediately if they

vomit ≥5 times within 24 h, show symptoms such as inability to eat or drink, aggravated dizziness and fatigue, or a significant reduction in urine output.

The observation group was additionally treated with aprepitan on this basis. Take 125 mg orally 60 min before the first day of chemotherapy treatment. Take 80 mg orally every morning on the second and third days. When administering the medicine, it should be swallowed whole. Do not chew or crush it. It can be taken with or without food. If a patient experiences vomiting and it occurs shortly after oral administration, there is no need to take a supplement on the same day. Patients with dysphagia can mix the contents of the capsule with an appropriate amount of apple sauce and take it immediately. The usage, dosage and other antiemetic drugs (palonosetron, dexamethasone) are the same as those of the control group.

2.3. Observation Indicators

(1) Chinese version Nausea, Vomiting and Retching Response Scale (R-INVR) score: To assess the severity of nausea and vomiting symptoms in the two groups of patients. The scale consists of three dimensions: nausea (3 items), vomiting (3 items), and retching (2 items). Each item is scored on a scale of 0 to 4 points, with a total score ranging from 0 to 32 points. The higher the score, the more severe the patient's nausea and vomiting symptoms.

(2) Remission rate of nausea and vomiting: The degree of remission of nausea and vomiting is differentiated in accordance with the standards of the World Health Organization (WHO). Complete remission (CR): No symptoms of nausea or vomiting; Partial remission (PR): Vomiting 1–2 times a day, with a significant reduction in nausea. Mild remission (MR): Vomiting 3 to 5 times a day, with no reduction in nausea. Ineffective (NR): Symptoms show no improvement or worsen. The total effective rate = (CR cases + P cases)/total cases × 100%.

(3) Life Function Index (FLIE) score: It assesses the impact of nausea and vomiting on the patient's daily life. The scale consists of two dimensions: the impact of nausea on life (9 items) and the impact of vomiting on life (9 items). Each item is scored from 1 to 7 points, with a total score range of 18 to 126 points. The higher the score, the smaller the impact of nausea and vomiting on the patient's daily life.

(4) Incidence of adverse reactions: Observe and record the adverse reactions that occurred during the treatment period in both groups of patients, including the occurrence of fatigue, constipation, headache, diarrhea and anorexia, and calculate the incidence of each adverse reaction.

2.4. Statistical Processing

Data were analyzed using SPSS30.0. Measurement data were expressed as $\bar{x} \pm s$. χ^2 and *t* tests were used. *p* value < 0.05 was considered statistically significant.

3. Results

(1) Comparison of R-INVR Scores between the Two Groups

The R-INVR score of the observation group was significantly lower than that of the control group, $p < 0.05$, and the difference was significant, as shown in Table 1.

Table 1. Comparison of R-INVR Scores (points, $\bar{x} \pm s$).

Group	Nausea	Vomiting	Retching	Total Score
Observation (n = 49)	5.32 ± 1.47	4.18 ± 1.23	3.05 ± 0.86	12.55 ± 2.91
Control (n = 49)	7.84 ± 1.96	6.37 ± 1.58	4.62 ± 1.14	18.83 ± 3.75
t	7.246	7.893	7.952	9.471
p	<0.001	<0.001	<0.001	<0.001

(2) Comparison of Nausea and Vomiting Remission Rates between the Two Groups

The remission rate of nausea and vomiting in the observation group was significantly higher than that in the control group ($p < 0.05$), with statistically significant differences, as shown in Table 2.

Table 2. Comparison of Nausea and Vomiting Remission Rates [n(%)].

Group	CR	PR	MR	Effective
Observation (n = 49)	3 2(65.31%)	12 (24.49%)	4 (8.16%)	44 (89.80%)
Control (n = 49)	18 (36.73%)	15 (30.61%)	11 (22.45%)	33 (67.35%)
χ^2		-		7.394
p		-		0.007

(3) Comparison of FLIE Scores between the Two Groups

The FLIE score in the observation group was significantly higher than that in the control group ($p < 0.05$), with statistically significant differences, as shown in Table 3.

Table 3. Comparison of FLIE Scores ($\bar{x} \pm s$).

Group	Impact of Nausea on Life	Impact of Vomiting on Life	Total Score
Observation (n = 49)	45.62 ± 6.73	43.87 ± 5.92	89.49 ± 11.25
Control (n = 49)	38.45 ± 5.84	36.93 ± 5.16	75.38 ± 9.67
t	5.783	6.214	6.582
p	<0.001	<0.001	<0.001

(4) Comparison of Adverse Reaction Rates between the Two Groups

The incidence of adverse reactions in the observation group was lower than that in the control group ($p < 0.05$), with statistically significant differences, as shown in Table 4.

Table 4. Comparison of Adverse Reaction Rates [n(%)].

Group	Fatigue	Constipation	Headache	Diarrhea	Anorexia
Observation (n = 49)	8 (16.33%)	6 (12.24%)	5 (10.20%)	4 (8.16%)	7 (14.29%)
Control (n = 49)	12 (24.49%)	10 (20.41%)	8 (16.33%)	7 (14.29%)	11 (22.45%)
χ^2		-			6.728
p		-			0.010

4. Discussion

Gynecological malignant tumors are significant diseases threatening women's health, with cervical cancer, endometrial cancer and ovarian cancer being the most common. In addition, they also include vaginal cancer and vulvar cancer, etc. [1]. Cervical cancer is often associated with persistent infection of high-risk human papillomavirus. Early symptoms are insidious. When it progresses to the middle or advanced stage, symptoms such as vaginal bleeding and pelvic pain are likely to occur. In severe cases, it can invade adjacent organs such as the bladder or rectum. Endometrial cancer mostly originates from endometrial glands and is typically characterized by vaginal bleeding after menopause. In the advanced stage, abdominal and pelvic metastases may occur. Ovarian cancer, due to its deep location and inconspicuous early symptoms, is often diagnosed at an advanced stage, with a relatively poor prognosis [2]. Chemotherapy is the main treatment method for advanced gynecological malignancies. Platinum-based drugs can effectively kill tumor cells and control the progression of the disease, but they can also cause various adverse reactions. Some patients reduce their treatment compliance or even interrupt the treatment course due to their inability to tolerate strong digestive tract reactions, thereby affecting the overall therapeutic effect of tumors [3]. Chemotherapy may also cause systemic reactions such as bone marrow suppression, liver and kidney function damage, neurotoxicity and fatigue, increasing the physical and mental burden on patients.

Aprepitan is a drug specifically used to prevent chemotherapy-related nausea and vomiting. It belongs to the neurokinin-1 receptor antagonist. The commonly used dosage form is capsule, and the main specifications are 80mg and 125mg. After oral administration, it is well absorbed in the gastrointestinal tract and is less affected by food. The peak blood drug concentration is reached about 4 h after taking the medicine. The bioavailability is approximately 60% to 65% [4]. This drug is mainly metabolized in the liver by the cytochrome P450 enzyme system. The metabolites are mainly excreted in feces, with a small amount excreted in urine. Its half-life is approximately 9-13 h [5]. After entering the human body, chemotherapy drugs will stimulate chromaffin cells in the gastrointestinal mucosa to release serotonin and activate neurokinin-1 receptors in the central nervous system [6]. The combined effect of the two will trigger nausea and vomiting reactions. Aprepitan can specifically bind to neurokinin-1 receptors in the central nervous system and the gastrointestinal tract, prevent neurokinin from binding to the receptors, block the signal transmission of nausea and vomiting, and inhibit the vomiting reflex from the source [7]. Because delayed nausea and vomiting are closely related to the activation of neurokinin-1 receptors, and traditional antiemetic drugs have difficulty acting on this target, the preventive effect of aprepitan on delayed nausea and vomiting is particularly prominent. In terms of safety and compatibility with combination therapy, aprepitan also has more advantages [8]. Some serotonin receptor antagonists, when combined with platinum-based chemotherapy drugs, increase the risk of adverse reactions in the central nervous system such as headache and dizziness, especially for older patients with gynecological malignancies or those with underlying diseases, whose

tolerance is more likely to be affected [9]. The metabolic pathways of aprepitan and platinum-based drugs overlap less, and the risk of drug interactions is lower. Moreover, its common adverse reactions are mostly mild constipation and fatigue, and it is less likely to increase the burden on the body when used in combination with conventional chemotherapy adjuvant drugs [10].

According to the data of this study, the levels of nausea, vomiting, retching and total score in the R-INVR scale of the observation group were all lower than those in the control group ($p < 0.001$), indicating that apirpitan effectively alleviated the severity of adverse digestive tract reactions in multiple dimensions. The reason lies in that it passes through the blood-brain barrier and blocks the signal transduction of substance *p* in the last region of the brain and the nucleus solitus. Thereby inhibiting the vomiting reflex triggered by chemotherapy drugs. In terms of symptom control, the complete remission rate (CR) of nausea and vomiting in the observation group reached 65.31%, and the total effective rate was 89.80%, which were significantly higher than 36.73% and 67.35% in the control group ($p = 0.007$), highlighting the positive role of aprepidem in improving the clinical antiemetic effect. Meanwhile, the total score of the FLIE scale in the observation group was higher than that in the control group ($p < 0.001$), indicating that the drug not only alleviated physical symptoms but also actually improved the patients' daily functional status, enabling them to better tolerate chemotherapy and maintain high levels of nutritional intake and physical strength.

In conclusion, apirapine effectively curbs the nausea and vomiting reflexes caused by chemotherapy by blocking the NK-1 receptor in the central nervous system, significantly improving the complete remission rate of symptoms and helping to maintain the quality of life of patients. It has considerable clinical value and promotion significance for the chemotherapy of gynecological malignant tumors.

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Writing—original draft, X.S., C.L., F.T., W.S. and X.Z.; writing—review and editing, X.S. and H.S. All authors have read and agreed to the published version of the manuscript.

Institutional Review Board Statement

This research was approved by the Ethics Review Committee of Scientific Research Projects of the Affiliated Hospital of Hebei University (Approval Date: January 9, 2023).

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Written informed consent has been obtained from the patient(s) to publish this paper.

Data Availability Statement

The datasets used in this article are all from the database of the Affiliated Hospital of Hebei University.

Conflicts of Interest

The authors declare no conflict of interest.

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