

The Therapeutic Effect of Capecitabine Single Drug Maintenance Therapy in the Advanced Breast Cancer

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Abstract: Objective: To analyze the efficacy of capecitabine (referred to as Cap) single-agent maintenance therapy in the advanced breast cancer. **Methods:** The subjects of the study were 50 patients with advanced breast cancer who were admitted to our hospital between March 2016 and March 2019. They were divided into groups A and B with 25 cases each. The subjects of these two groups were treated conventional method, respectively. And then, Capecitabine maintenance therapy was continued for group A, clinical observation for groups B. Progression-free survival(PFS) was compared between the two groups. **Results:** The median PFS was 14.2 months for group A and 8.9 months for group B ($P < 0.05$). The complication rate of group A was 24.0% compared to that of group B was 22.0% ($P > 0.05$). **Conclusion:** The patients with advanced breast cancer who received Cap maintenance therapy were benefited from better curative effect and controllable complications, which has high promotion value.

Keywords: Capecitabine, Single drug maintenance, Advanced breast cancer, PFS

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1 Introduction

Breast cancer is a clinically high incidence of gynaecological tumours, which is the main type of disease in female patients. Clinically, this disease is treated with a combination of surgery, radiotherapy and chemotherapy. However, conventional treatment

could not control advanced breast cancer. In addition, the treatment principle of advanced breast cancer is to prolong the life cycle and improve the quality of life. Thus, maintenance therapy is often used^[1]. Combination therapy is the main maintenance treatment for the disease, but there are many adverse drug reactions and high treatment costs. The studied population consisted of 50 patients with advanced breast cancer who were admitted to the hospital between March 2016 and March 2019 to explore the efficacy of Cap single drug maintenance.

2 Data and methods

2.1 General information

The subjects was 50 patients with advanced breast cancer who were treated in our hospital between March 2016 and March 2019. They were divided into group A and B with 25 cases each. Among them, the age of group A is ranging from 34 to 66 years old, with an average of (50.41±1.24) years. The course of the disease was 5 to 15 months, with an average of (7.54±0.14) months. The diseases were categorized into 2 cases of medullary carcinoma, 2 cases of adenocarcinoma, 7 cases of simple cancer, 10 cases of invasive ductal carcinoma and 4 other cases. The age of group B is ranging from 33 to 65 years old, with an average of (50.24±1.34) years. The course of the disease was 6 to 17 months, with an average of (7.84±0.21) months. The diseases were categorized into 3 cases of medullary carcinoma, 2 cases of adenocarcinoma, 8 cases of simple breast cancer, 11 cases of invasive ductal carcinoma and 1 other case. There was no difference in comparison ($P > 0.05$).

2.2 Methods

Both groups received conventional chemotherapy, Drugs used for chemotherapy include Paclitaxel, docetaxel, gemcitabine, vinorelbine, albumin-paclitaxel, et al. And then, groups B accept clinical observation, The patient's condition was observed, and symptomatic treatment was given. Meanwhile, Group A was treated with Cap (National Medicine Permit No: J20080101, Shanghai Roche Pharmaceuticals) as maintenance therapy. The dose is 1000 mg/m² and taken orally with warm water 0.5 hours after the meal. It was taken 2 times a day, continued for 1–14 days, rested for 7 days and recorded as 1 cycle.

2.3 Criteria for efficacy evaluation: RECIST 1.1

Complete remission (referred as CR); partial

remission (referred as PR); stable disease (referred as SD); progressive disease (referred as PD)^[2]. Disease Control Rate(DCR)=CR+PR+SD.

2.4 Analysis statistics

Data processing was performed using SPSS 16.0 software, the probability was expressed as [%], the test method was x² value and the statistical significance was $P < 0.05$.

3 Results

3.1 Comparison of efficacy

After 6 cycles of chemotherapy, the DCR of was 73.5.0% for group A and 76.0% for group B ($P > 0.05$) as shown in Table 1.

Table 1. After 6 cycles of chemotherapy, Comparative DCR [n/%]

Groups	Cases	CR	PR	SD	PD	DCR
GroupA	25	3 (8.0)	13 (16.0)	2 (24.0)	7 (4.0)	72.0 (18/25)
GroupB	25	2 (8.0)	14 (56.0)	3 (12.0)	6 (24.0)	76.0 (19/25)
x ²	-	-	-	-	-	22.853
P	-	-	-	-	-	0.42

After the subjects of these two groups were treated conventional method, Capecitabine maintenance therapy was continued for group A, clinical observation for groups B. We discovered that group A experienced 14.2 months of median PFS vs 8.9 months with group

B ($P = 0.024$).

3.2 Comparison of complication rate

The complication rate was 24.0% in group A and 22.0% in group B ($P > 0.05$), as shown in Table 2.

Table 2. Comparative complication rate [n/%]

Groups	Cases	Hand-foot syndrome	Neutrophil reduction	Liver damage	Hair loss	Incidence rate
Group A	25	4 (16.0)	16 (64)	5 (20)	1 (4.0)	24.0
Group B	25	2 (8.0)	14 (56.0)	3 (12.0)	3 (12.0)	22.0
x ²	-	-	-	-	-	28.594
P	-	-	-	-	-	0.24

4 Discussion

The main treatment for advanced breast cancer is combined with chemotherapy. Despite better results can be obtained, the remission period is shorter, there are obvious adverse reactions and the tolerance is poor^[3]. In order to ensure the therapeutic effect of patients with this disease, it is desired to actively seek for low-toxic and effective maintenance therapy to improve clinical tolerance.

Cap is a commonly used drug for the treatment of this disease. It belongs to a new derivative of fluorouracil

(FU). After entering the body, it can be converted to 5-FU by the enzyme-linked reaction which catalyzed by thymidine phosphorylase (TP) in the tumour. The TP content in the tumour is high, which can transform Cap into a large amount of 5-FU in the cells to exert its anti-tumour activity. It is highly damaging to tumours but does not exert damage to normal tissue. The aim of maintenance therapy is to control disease while targeted therapy and endocrine therapy are more commonly used maintenance therapies, but they have limitations. The former has high treatment costs; thus, it cannot be promoted while the latter is limited to metastatic

tumours and needs to meet hormone receptor-positive conditions^[4]. Whereas, Cap maintenance therapy is highly safe, convenient administration and low treatment cost. It can be used as a routine maintenance treatment plan for primary hospitals and is not affected by factors such as tumour type and hormone receptors.

Results: The median PFS of group A (14.2 months) was longer than that of group B (8.9 months) ($P < 0.05$). This indicates the Cap maintenance therapy can delay tumour development and has a better prognosis. The disease progresses in advanced breast cancer, and the lesion can be severely metastasized within a few days or months. Orally taken Cap can kill tumour cells and control the progression of the disease. The complication rate in group A (24.0%) was lower than that in group B (22.0%) ($P > 0.05$). It indicates that the drug safety of Cap is higher because it does not have serious toxic and side effects. The mechanism of pharmacological action is completed by 5-FU. The drug itself does not affect hemodynamic and organ function, which is suitable for prolonged treatment. If the patient's tumour continues to grow, and the effect is not good, it can be combined with drugs such as docetaxel to ensure its

efficacy. The results are consistent with the research by Gu Weiwei^[5]. It suggests that Cap single drug maintenance can effectively treat the disease, control tumour deterioration, reduce complications and can be actively promoted in clinical practice.

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