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Effectiveness and Safety of Combined Chemotherapy and Biological Targeted Therapy in the Treatment of Breast Cancer

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Abstract: Purpose: To evaluate the effectiveness and safety of combined chemotherapy and biological targeted therapy in breast cancer patients. **Methods:** A total of 72 patients diagnosed with breast cancer confirmed by pathological examination and hospitalized from February 2023 to February 2024 were selected. They were randomly divided into two groups using systematic randomization: control group (n = 36) and observation group (n = 36). The control group received chemotherapy, while the observation group received combined chemotherapy and biological targeted therapy. The incidence of complications and quality of life scores were compared between the two groups. **Results:** After treatment, the incidence of complications in the observation group was lower compared to the control group (11.11% vs. 30.56%, $P < 0.05$). There was no significant difference in quality of life indicators between the two groups before treatment ($P > 0.05$). However, after treatment, the quality of life scores in the observation group were significantly higher compared to the control group ($P < 0.05$). **Conclusion:** Combined chemotherapy and biological targeted therapy in breast cancer patients have remarkable effects in improving local recurrence, preventing distant metastasis, and enhancing overall quality of life with high safety. This approach holds significant value for reference and promotion.

Keywords: Chemotherapy; Biological targeted therapy; Breast cancer; Effectiveness; Safety.

Breast cancer is one of the most common gynecological malignancies, with research data indicating an annual increase in incidence ranging from 2% to 8%, ranking it as the top malignant tumor. In recent years, due to the trend of younger age among breast cancer patients, the aggressiveness of cancer cells and the recurrence rate have been increasing, leading to a lower cure rate for breast cancer. For early-stage breast cancer patients, surgical treatment is mainly adopted. Modified radical mastectomy and breast-conserving surgery can effectively remove lesion tissues and prolong patient survival. However, in order to further improve treatment outcomes, postoperative chemotherapy and radiotherapy are necessary. With the continuous advancement and development of medical technology, there is increasing attention from society on treatment measures for diseases. Moreover, the clinical understanding of molecular biology and diagnostic and therapeutic levels has been continuously improving,

leading to breakthrough progress in controlling mortality rates during breast cancer treatment. Due to the rapid development of targeted biological therapy measures, targeting human epidermal growth factor receptor 2 (HER2) overexpression has gradually become a specific target for breast cancer treatment, which is beneficial for further improving clinical treatment outcomes. The specific content summary is as follows:

1. Data and Methods

1.1 General Information

The study was conducted from February 2023 to February 2024. The enrolled subjects were breast cancer patients confirmed by pathological examination. A total of 72 enrolled patients were randomly assigned into two groups using systematic randomization: the control group (n = 36) and the observation group (n = 36). The summarized basic information is as follows. In the control group, the age of enrolled patients ranged from 27 to 72 years, with a mean age of (49.68±3.65) years; the duration of the disease ranged from 2 to 10 months, with an average duration of (6.52±1.76) months. Pathological evaluation revealed 28 cases of invasive ductal carcinoma and 8 cases of invasive lobular carcinoma. Tumor staging results were as follows: 7 cases of stage I, 20 cases of stage II, and 9 cases of stage III. In the observation group, the age of enrolled patients ranged from 31 to 68 years, with a mean age of (48.85±2.92) years; the duration of the disease ranged from 1 to 12 months, with an average duration of (6.29±1.62) months. Pathological evaluation revealed 24 cases of invasive ductal carcinoma and 12 cases of invasive lobular carcinoma. Tumor staging results were as follows: 6 cases of stage I, 19 cases of stage II, and 11 cases of stage III. The general data comparison between the two groups showed no significant difference ($P > 0.05$), indicating comparability for research purposes. The study was approved by the hospital ethics committee. Inclusion Criteria : ① Patients confirmed with breast cancer by pathological examination; ② Unilateral breast lesions; ③ No evidence of cancer cell dissemination at admission; ④ Informed consent signed voluntarily by patients after understanding the study; ⑤Complete clinical data. Exclusion Criteria: ①Patients with bilateral breast cancer lesions; ② Patients with severe systemic infections; ③ Patients with other types of malignant tumors; ④ Patients with severe organ dysfunction; ⑤ Patients who withdrew from the study midway.

1.2 Methods

After diagnosis, both groups of patients underwent early modified radical mastectomy. Following surgery, patients in the control group received adjuvant chemotherapy. The chemotherapy regimen consisted of cyclophosphamide, epirubicin, and docetaxel. Cyclophosphamide was sourced from Tonghua Maoxiang Pharmaceutical Co., Ltd., with National Drug Approval Number H22022673. It was administered orally at a dose of 2-4 mg/(kg•d) for 10-14 days (with a 1-2 week rest period before repeating). Epirubicin was sourced from Zhejiang Haizheng Pharmaceutical Co., Ltd., with National Drug Approval Number H19990279. It was administered intravenously at a dose of 50-60 mg/m^2 after every 4 cycles, followed sequentially by docetaxel. Docetaxel was sourced from China Pharmaceutical Research and Development Center Co., Ltd., with National Drug Approval Number H20113410. It was administered intravenously at a dose of 60-75 mg/m^2 using a drip infusion method, with infusion time controlled within 1 hour, and repeated every 3 weeks. Radiation therapy was delivered using three-dimensional conformal techniques, with a dose of 2 Gy per session, administered 5 times per week.

The observation group received targeted therapy with trastuzumab (Herceptin) based on the treatment regimen of the control group. The initial dose of trastuzumab was set at 8 mg/kg in the first week, followed by dose adjustment to 6 mg/kg. Trastuzumab was administered intravenously every 3 weeks for a duration of 1 year.

1.3 Observational Indicators

Quality of Life: The evaluation was conducted using the World Health Organization Quality of Life Assessment Instrument-Short Version (WHOQOL-BREF). This assessment tool measures changes in patients' quality of life before and after treatment across various domains including physical, psychological, social, and environmental aspects, as well as overall health. Each domain is scored from 0 to 100, with higher scores indicating better quality of life. The scores are positively correlated with the patients' quality of life.

Incidence of Complications: Analysis was performed to determine whether patients experienced symptoms such as upper limb lymphedema, seroma formation under the flap, flap necrosis, or infection. The incidence rate was calculated based on the occurrence of these symptoms.

1.4 Statistical Analysis

Data from the research experiment were analyzed using the SPSS 25.0 software package. Categorical data were subjected to the chi-square (χ^2) test and presented as (n, %), while continuous data were analyzed using the t-test and expressed as (mean ± standard deviation). A significance level of $P < 0.05$ was considered statistically significant in the study.

2. Results

2.1 Comparison of Quality of Life Scores between the Two Groups

Before treatment, a comparative evaluation of the quality of life between the two groups was conducted, showing no significant differences in various indicators ($P > 0.05$). After implementing corresponding treatment measures, there was an improvement in the quality of life of the enrolled subjects. Moreover, the increase in various indicators in the observation group was greater than that in the control group ($P < 0.05$), as shown in **Table 1**.

Table 1. Comparison of Quality of Life between Groups ($\bar{x} \pm s$, points)

Group	Social Domain		Environmental Domain		Physical Domain		Physical Domain		Overall Health	
	Before	After	Before	After	Before	After	Before	After	Before	After
Observation Group (n = 36)	42.85± 5.15	64.28± 4.64	46.15± 4.15	67.82± 7.11	44.28± 4.18	67.18± 4.39	35.44± 4.72	63.18± 4.63	44.22± 4.63	71.22± 5.09
Control Group (n = 36)	42.43± 5.36	61.05± 3.93	45.55± 4.39	63.63± 7.42	45.58± 4.39	64.58± 5.15	36.93± 4.28	60.52± 4.18	45.68± 5.15	66.75± 4.92
t	0.339	3.187	0.596	2.446	1.287	2.305	1.403	2.559	1.265	3.789
P	0.736	0.002	0.553	0.017	0.202	0.024	0.165	0.013	0.210	0.001

2.2 Statistical Analysis of Complication Incidence Rate

The measured values of this group's indicators were 11.11% and 30.56% respectively. The observation group had a lower incidence rate compared to the control group, with a significant difference ($P < 0.05$), as shown in **Table 2**.

Table 2. Comparison Analysis of Complication Incidence Rate (n, %)

Group	Cases	Upper Limb Lymphedema	Seroma under Flap	Flap Necrosis	Infection	Incidence Rate
Observation Group	36	1	1	1	1	4(11.11)
Control Group	36	3	4	2	2	11(30.56)
X^2	--	--	--	--	--	4.126
P	--	--	--	--	--	0.042

Discussion

Breast cancer is a common malignant tumor, and in recent years, its incidence has been steadily increasing. It is classified into early, middle, and late stages as a systemic disease. For early and middle stage breast cancer patients, surgical treatment can remove tumor tissue, inhibit disease progression, and improve survival time within five years. Early surgical treatment is crucial for improving prognosis. By selecting appropriate surgical procedures based on tumor location, staging, and individual condition, it is an effective means to reduce recurrence and mortality rates. In recent years, with the continuous advancement and development of medical technology, minimally invasive surgical procedures have achieved ideal results. While completely removing tumors, they can minimize the surgical area, reduce surgical trauma, ensure chest aesthetics, and reduce damage to upper limb function, thus preventing the occurrence of complications.

The results of this study showed that before treatment, there were no significant differences in the quality of life between the two groups ($P > 0.05$). After treatment, the quality of life scores in the observation group were higher than those in the control group, and the incidence

of postoperative complications was lower than that in the control group. The differences in various indicators were significant ($P < 0.05$). The reasons for this analysis are as follows: After breast cancer surgery, adjuvant treatment options mainly include chemotherapy and targeted therapy. There is a variety of chemotherapy regimens available in clinical practice, which can eliminate micrometastatic lesions that surgery cannot remove and have an ideal inhibitory effect on tumor cell activity, thus preventing distant metastasis of tumors. The efficacy of chemotherapy after breast cancer surgery has been clinically confirmed, but most chemotherapy drugs have toxicity, causing considerable damage to patients' organ functions, which may affect surgical outcomes. Radiotherapy, as an important treatment modality for malignant tumors, can effectively suppress tumor recurrence by delivering radiation therapy to local tumor lesions. However, it may increase the risk of cardiac events leading to death. Combined chemotherapy and radiotherapy are common treatment modalities for breast cancer, significantly enhancing the surgical outcomes. However, excessive use of combined chemotherapy and radiotherapy may increase the risk of complications, necessitating the use of adjunct drug therapy. Targeted therapy is a focus of tumor research. The trastuzumab used in this study is a recombinant DNA-derived humanized monoclonal antibody that acts on human epidermal growth factor receptor 2 (HER-2) in the patient's body. By targeting HER2-positive breast cancer, trastuzumab can further improve HER2 attachment, inhibit HER2 production, and have an ideal inhibitory effect on tumor cell proliferation and growth, thereby improving disease-free survival and extending survival time for HER2-positive breast cancer patients.

This study also confirms that breast cancer patients undergoing combined chemotherapy and targeted therapy after surgery have ideal outcomes, effectively inhibiting tumor progression, comprehensively improving the function of the affected upper limbs, and enhancing quality of life.

In conclusion, combined chemotherapy and targeted therapy for breast cancer patients have high safety and efficacy, improving short- and long-term outcomes, further increasing long-term survival rates, and overall quality of life. Therefore, it holds significant value for clinical application.

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