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Study on the Efficacy and Quality of Life Impact of Combination Adjuvant Chemotherapy with Epirubicin and Docetaxel for Breast Cancer Patients after Radical Mastectomy

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Abstract: *Objective*: To explore and analyze the clinical effect of combination adjuvant chemotherapy with epirubicin and docetaxel for patients after radical mastectomy for breast cancer. *Methods*: This study enrolled 60 patients between May 2022 and December 2024, who were randomly allocated into two equal treatment groups (n = 30 each). The control group received standard chemotherapy, whereas the observation group was treated with a combined adjuvant regimen of epirubicin and docetaxel. Therapeutic outcomes were systematically compared between the groups. *Results*: The comparative analysis of chemotherapy regimens revealed significant intergroup differences in multiple outcome measures. The observation group demonstrated superior clinical efficacy (96.67% vs 80.00%, $P < 0.05$) alongside a more favorable safety profile (adverse reaction incidence: 3.33% vs 20.00%, $P < 0.05$). Metabolic assessments showed better glycemic control in the observation group, with both fasting and postprandial blood glucose levels being significantly lower than controls ($P < 0.05$), while maintaining comparable values to pretreatment baselines ($P > 0.05$). Furthermore, quality of life assessments indicated significantly better outcomes in the observation group compared to controls ($P < 0.05$). *Conclusion*: The combination of epirubicin and docetaxel as adjuvant chemotherapy for patients after radical mastectomy for breast cancer has significant clinical effects, can improve patients' quality of life, and has high safety. It is worthy of adoption.

Keywords: Radical mastectomy for breast cancer; Epirubicin; Docetaxel; Adjuvant chemotherapy; Clinical effective rate

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1. Introduction

Breast cancer is a common malignant tumor among women, and its incidence rate is increasing year by year, posing a great threat to women's health [1]. Clinically, radical mastectomy is the main treatment method, but there may be residual microscopic cancer cells in the patient's body after surgery, posing a risk of recurrence and

metastasis. Therefore, postoperative adjuvant chemotherapy is very important, as it can consolidate the surgical effect and reduce the possibility of recurrence, thereby significantly improving the long-term survival rate of patients. Epirubicin and docetaxel are commonly used chemotherapy drugs in clinical practice, and they can form a synergistic complement. Their combination chemotherapy regimen has shown good prospects in adjuvant treatment for breast cancer in recent years [2]. However, existing studies have focused more on short-term efficacy observations, and there is still a lack of research on improving patients' long-term quality of life and exploring the mechanism of chemotherapy-related metabolic disorders [3]. Based on these situations, this study included 60 patients to compare the feasibility of different chemotherapy regimens to provide more valuable references for clinical practice. See below for details.

2. Materials and methods

2.1. General information

This study enrolled 60 patients between May 2022 and December 2024, randomly allocated into two equal-sized groups (n = 30 each) according to treatment protocols. The observation group comprised patients aged 56–72 years (mean 65.56 ± 4.56) with disease duration of 3–5 years (mean 3.56 ± 0.23), including 12 stage I, 10 stage II, and 8 stage III breast cancer cases. The control group showed similar demographics: Age 56–74 years (mean 65.59 ± 4.34), disease duration 3–5 years (mean 3.66 ± 0.21), with 13 stage I, 10 stage II, and 7 stage III cases. Intergroup comparisons revealed no significant differences ($P > 0.05$), confirming baseline comparability.

Inclusion criteria: (1) Pathologically confirmed diagnosis of breast cancer [4]; (2) Meeting the surgical indications for radical mastectomy; (3) Informed consent from the patient and their family, with signed informed consent forms. Exclusion criteria: (1) Those with severe organ dysfunction; (2) Those with diabetes or other endocrine system diseases; (3) Those allergic to epirubicin, docetaxel, or other chemotherapy drugs; (4) Those who have recently received other anti-tumor treatments.

2.2. Methods

Control group: Conventional chemotherapy regimen (cyclophosphamide + fluorouracil). The dose of cyclophosphamide (Jiangsu Hengrui Medicine Co., Ltd.; National Medical Approval Number H20023036) was 750mg/m^2, administered intravenously once every 21 days as a cycle. Fluorouracil (Tianjin Jinyao Pharmaceutical Co., Ltd.; National Medical Approval Number H12020959) was administered at a dose of 500mg/m^2 as a continuous intravenous infusion for 3–5 days per cycle, with a total of 6 cycles of chemotherapy. Patients' conditions were observed during the treatment, and in case of severe adverse reactions, medication was immediately stopped. Supportive treatment measures such as antiemetic therapy, gastric protection, and hydration were provided, and patients' heart function was closely monitored.

Observation group: Epirubicin + docetaxel combination adjuvant chemotherapy regimen. Epirubicin (Zhejiang Haizheng Pharmaceutical Co., Ltd., National Medical Approval Number H20041211) was administered at a dose of 60mg/m^2 intravenously once every 21 days as a cycle. Docetaxel (Jiangsu Hengrui Medicine Co., Ltd.; National Medical Approval Number H20030561) was given at a dose of 75mg/m^2 intravenously once every 21 days as a cycle, with a total of 6 cycles of chemotherapy [5]. Dexamethasone (Guangdong Sancai Pharmaceutical Group Co., Ltd.; National Medical Approval Number H44024276) was orally administered at 8mg twice a day, starting from the day before, the day of, and the day after docetaxel administration to prevent allergic reactions and fluid

retention. Patients' conditions were observed during the treatment, and medication was immediately stopped in case of severe adverse reactions. Supportive measures such as antiemetic therapy, gastric protection, and hydration were provided, and patients' heart function was closely monitored.

2.3. Observation indicators

(1) Treatment efficacy was compared between groups using RECIST (Response Evaluation Criteria in Solid Tumors), with outcomes categorized as complete response (CR), partial response (PR), stable disease (SD), or progressive disease (PD). The overall response rate (ORR), defined as (CR + PR)/total cases × 100%, served as the primary efficacy endpoint.

(2) Compare the incidence of adverse reactions between the two groups, including myelosuppression, such as leukopenia, thrombocytopenia, etc., gastrointestinal reactions, such as nausea, vomiting, diarrhea, etc., cardiac toxicity, liver and kidney damage, and other adverse reactions.

(3) Glycemic abnormalities were compared between groups by measuring fasting blood glucose (FBG) and 2-hour postprandial blood glucose (2h-PBG) levels at baseline and one-month post-chemotherapy. Abnormal glucose metabolism was defined as FBG ≥ 7.0 mmol/L and/or 2h-PBG ≥ 11.1 mmol/L according to standard diagnostic criteria.

(4) Quality of life (QoL) was compared between the two groups using the Functional Assessment of Cancer Therapy-Breast (FACT-B) scale. This instrument evaluates four key domains: Physical well-being, social/family well-being, emotional well-being, and functional well-being. The total possible score ranges from 0 to 136, with higher scores reflecting better QoL outcomes.

2.4. Statistical methods

All data obtained in this study were processed using SPSS 22 statistical software. Measurement data were expressed as mean ± standard deviation (SD), conforming to a normal distribution, and analyzed using the *t*-test. Count data were expressed as the number of cases and percentage (%), and analyzed using the chi-square test. A P-value < 0.05 was considered statistically significant.

3. Results

3.1. Comparison of clinical efficacy

Table 1 demonstrates a significantly higher clinical efficacy rate in the observation group (96.67%) compared to the control group (80.00%), with statistical significance ($P < 0.05$).

Table 1. Comparison of clinical efficacy between the two groups of patients [*n* (%)]

Group	Number of cases (*n*)	CR	PR	SD	PD	Total effective rate
Observation group	30	16 (53.33)	13 (43.33)	1 (3.33)	0 (0.00)	29 (96.67)
Control group	30	12 (40.00)	12 (40.00)	4 (13.33)	2 (6.67)	24 (80.00)
χ^2	-	-	-	-	-	4.043
P	-	-	-	-	-	0.044

3.2. Comparison of adverse reactions

Table 2 demonstrates a significantly lower incidence of adverse reactions in the observation group (3.33%) compared to the control group (20.00%), with this difference reaching statistical significance ($P < 0.05$).

Table 2. Comparison of adverse reactions between the two groups of patients [*n* (%)]

Group	Number of cases (*n*)	Bone marrow suppression	Gastrointestinal reaction	Cardiotoxicity	Liver and kidney function damage	Total incidence rate
Observation group	30	0 (0.00)	1 (3.33)	0 (0.00)	0 (0.00)	1 (3.33)
Control group	30	1 (3.33)	4 (13.34)	0 (0.00)	1 (3.33)	6 (20.00)
χ^2	-	-	-	-	-	4.043
P	-	-	-	-	-	0.044

3.3. Comparison of blood glucose levels before and after treatment

As shown in **Table 3**, post-treatment fasting blood glucose (FBG) and 2-hour postprandial blood glucose (2h-PBG) levels were significantly lower in the observation group compared to the control group ($P < 0.05$). However, no statistically significant difference was observed when compared to baseline values ($P > 0.05$).

Table 3. Comparison of blood glucose levels before and after treatment between the two groups of patients (mean ± SD)

Group	Number of cases (*n*)	Fasting blood glucose (mmol/L)		2-Hour postprandial blood glucose (mmol/L)	
		Before chemotherapy	After chemotherapy	Before chemotherapy	After chemotherapy
Observation group	30	5.56 ± 1.11	5.63 ± 1.15	8.78 ± 1.12	8.69 ± 1.16
Control group	30	5.52 ± 1.12	6.41 ± 1.16	8.67 ± 1.11	9.82 ± 1.19
t	-	0.139	2.615	0.382	3.724
P	-	0.890	0.011	0.704	0.001

3.4. Improving quality of life outcomes following intervention in the observation group

A comparison of pre- and post-treatment quality of life scores revealed that the observation group demonstrated significantly higher QoL scores than the control group following the intervention ($P < 0.05$, **Table 4**).

Table 4. Comparison of quality of life scores before and after treatment between the two groups of patients (mean ± SD)

Group	Number of cases (*n*)	Quality of life score (points)	
		Before chemotherapy	After chemotherapy
Observation group	30	78.45 ± 5.67	118.23 ± 5.15
Control group	30	78.41 ± 5.48	97.34 ± 5.19
t	-	0.028	15.649
P	-	0.978	0.001

4. Discussion

Breast cancer, as the most common malignant tumor among women worldwide, has a grim development trend. Despite continuous improvements in early diagnosis techniques and comprehensive treatment levels, the 5-year survival rate for patients with advanced breast cancer remains below 30%, posing significant challenges to clinical treatment [6]. Surgical radical resection plays a crucial role in breast cancer treatment, but residual micrometastases after surgery are key factors leading to recurrence. Therefore, adjuvant chemotherapy has become an indispensable treatment component. Among various chemotherapy regimens, the combination of anthracyclines and taxanes has gradually become a routine choice for adjuvant breast cancer therapy, and the combined use of epirubicin and docetaxel is widely used in clinical practice [7]. Epirubicin is a typical anthracycline drug that embeds into the DNA double helix of tumor cells, interferes with the normal function of topoisomerase II, and thereby blocks DNA replication and transcription processes. Simultaneously, this drug can also generate free radicals, trigger lipid peroxidation reactions, and induce tumor cell apoptosis. Docetaxel, as a representative of taxanes, promotes microtubule protein polymerization while inhibiting its depolymerization, disrupting the normal formation of the mitotic spindle, and arresting tumor cells in the G2/M phase. The combination of these two drugs has significant advantages. Epirubicin mainly acts on the early stage of DNA synthesis, while docetaxel targets the mitotic phase. These two drugs complement each other in the cell cycle, significantly improving the pathological complete response rate in locally advanced breast cancer and surpassing single-drug treatment regimens [8].

The results of this study showed that the clinical effective rate of the observation group was 96.67%, which was higher than the 80.00% of the control group ($P < 0.05$), indicating that the adjuvant chemotherapy of epirubicin combined with docetaxel had a better effect on patients after radical mastectomy for breast cancer. Epirubicin exerts its antitumor effect by inhibiting DNA replication and transcription, while docetaxel induces apoptosis by affecting microtubule proteins, and the combination of the two can synergistically enhance efficacy [9]. At the same time, the incidence of adverse reactions in the observation group was 3.33%, which was lower than the 20.00% in the control group ($P < 0.05$), and the degree was lighter, which may be related to the reasonable drug combination and pretreatment. Post-intervention analysis revealed significantly lower fasting and 2-hour postprandial blood glucose levels in the observation group compared to controls ($P < 0.05$). However, no significant differences were observed when comparing these values to pre-treatment levels ($P > 0.05$), suggesting the treatment regimen had minimal impact on glycemic control. Breast cancer patients may experience blood glucose fluctuations during chemotherapy due to factors such as stress response and drug side effects. The results of this study showed that the combined chemotherapy regimen did not cause significant increases or decreases in blood glucose, indicating that the regimen has a smaller impact on the endocrine system of patients and higher safety [10]. Moreover, quality of life is an important indicator to evaluate cancer treatment. Post-treatment analysis revealed significantly higher quality of life scores in the observation group compared to controls ($P < 0.05$), suggesting that the adjuvant chemotherapy regimen combining epirubicin and docetaxel may enhance postoperative quality of life in breast cancer patients following radical mastectomy.

5. Conclusion

In summary, epirubicin combined with docetaxel for adjuvant chemotherapy after radical mastectomy for breast cancer has good efficacy and is a safe and effective chemotherapy regimen, which is suitable for clinical promotion and application.

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Disclosure statement

The authors declare no conflict of interest.

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