Effect of lymphedema prevention program based on theory of Knowledge-attitude-practice on postoperative breast cancer patients: a randomized clinical trial

Research Proposal

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1 INTRODUCTION AND BACKGROUND

With an estimated 19.3 million new cancer cases worldwide in 2020, breast cancer in women overtook lung cancer as the most common cancer for the first time. Surgery is the most commonly used treatment for Breast Cancer, but it can lead to some complications, such as wound bleeding, infection, subcutaneous effusion, flap necrosis, limb dysfunction and Breast cancer-related Lymphedema (BCRL). Among them, BCRL can lead to upper limb dysfunction, muscle weakness, appearance impairment, anxiety and depression and other physical and psychological problems in breast cancer patients, which seriously affect the postoperative rehabilitation and quality of life of patients, and BCRL is difficult to cure once it occurs. According to relevant literature reports, the incidence of BCRL is about 21.4%, which is a widespread problem.

BCRL is due to a variety of breast cancer treatment methods damage the lymphatic system, resulting in lymphatic vessel fracture and morphological changes in the affected limb, so that the lymphatic fluid can not smoothly return, so that the affected arm of patients with swelling and pain, severe cases will cause infection and tissue fibrosis. At present, physical treatment, drug treatment or surgery can improve edema symptoms in different degrees, but due to the longer course of treatment, high cost, difficult lasting effect and other problems, so that many patients can not adhere to the treatment. BCRL has been recognized as a difficult point in the rehabilitation of patients, and medical workers need to pay attention to it.

Due to the lack of understanding of lymphedema in most patients, the initial manifestations of BCRL are easy to be ignored by patients, resulting in difficulties in the early prevention and detection of edema. Some domestic studies investigated local patients with the knowledge of lymphedema prevention after breast cancer surgery, and the results showed that the patients had a poor grasp of relevant knowledge, with an average score rate of 25.18%, which was significantly lower than the international median awareness rate of lymphedema. Since BCRL is difficult to cure once it occurs, researchers pay more and more attention to the prevention and early intervention of lymphedema, and improve the awareness and education of patients about the risk of lymphedema, which has become a necessary measure to improve the quality of life of breast cancer patients.

At present, knowledge, attitude and practice theory is widely used in rehabilitation guidance and education of patients. Based on KAP theory and combined with the best evidence of upper limb lymphedema prevention in patients after breast cancer surgery, this study plans to formulate a prevention plan for upper limb lymphedema in patients after breast cancer surgery, and apply this plan in clinical practice, so as to improve patients' cognition of lymphedema and promote patients to master and take positive rehabilitation behaviors. So as to reduce the incidence of upper limb lymphedema, improve the grip strength and function of the affected upper limb, and improve the quality of life of patients.

2 METHODS

2.1 Design

This study was a randomized controlled experimental study. The study population included breast cancer patients who received advanced chemotherapy in a Class

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A public hospital in Xi 'an, Shaanxi Province, China from March 2020 to November 2020.

2.2 Sample

Inclusion criteria: (1) Female patients were ≥18 years old; (2) Pathological puncture confirmed breast cancer with unilateral, no recurrence, and no metastasis; (3) Patients with clinical TNM stage Ⅰ~Ⅲ; (4) Patients with proposed surgery and 6 or more chemotherapy; (5) The patient was conscious and aware of his condition, with no cognitive impairment or communication problems.Exclusion criteria: (1) Patients who had cancer other than breast cancer; (2) Patients who had history of arm or neck trauma, infection or surgery; (3) Patients who had serious diseases such as cardiovascular, cerebrovascular, liver, kidney, etc; (4) Patients who had upper limb disability or the affected limb has edema before surgery; (5) Patients who had thrombus in the blood vessels of the affected limb.

2.3 Power analysis

This study used PASS 15.0 to calculate the sample size, using two-sided test, α =0.05 and 1- β =0.8. According to the literature, , P1 was taken as 30% and P2 = 5%. The final calculation yielded N1=N2=44, considering the 20% loss to follow-up rate after surgery, and the final total sample size was set at 106 cases, with 53 cases in the intervention group and 53 cases in the control group.

2.4 Randomization

The unit admitting breast cancer was divided into four medical groups, whose members had been trained in homogeneous surgical operations. As each medical group managed fixed patients and wards, patients in different medical groups were treated in different wards. To avoid contamination between the intervention and control groups, the study was conducted in regional randomized groups based on departmental medical groups (block size is 4). Four labels were placed in four opaque envelopes, two with 0 and the other two with 1. Four physicians representing their respective groups drew the envelopes, and the patients enrolled in the two medical groups with "0" were designated as the control group, while the other two groups were designated as the intervention group.

3. Procedure

The control group carried out normal perioperative and chemotherapy nursing process, while the intervention group used upper limb lymphedema prevention program to manage patients, The specific implementation process was as follows：

Coming for surgery: A PPT lecture; 2. A seminar; 3. Patients were given a lymphedema prevention brochure; 4. Diary cards for exercise is given and instruct patients to fill out daily; 5. Establish a WeChat group.

The first chemotherapy:1. Review diary card and provide guidance and education. 2. A PPT lecture; 3. A seminar; 4. Play functional exercise videos in the recovery room; 5. Rehabilitation volunteers come to the ward to form mutual help groups with patients under the guidance of subject team members; 6. Instruct regular exercise and avoid behaviors that can lead to lymphedema. 7. Ask about the exercise and whether there is any swelling and discomfort and give guidance.

The second chemotherapy: 1. A PPT lecture; 2. A seminar; 3. Play functional exercise videos in the recovery room.

The third chemotherapy: 1. Routine nursing; 2. Assess patients' knowledge of

lymphedema prevention and exercise compliances; 3. Play functional exercise videos in the recovery room.

3.1 Data collection

he data collection personnel were trained uniformly, and the collection personnel were not aware of the grouping of patients. Before the intervention, the whole process of the prevention program, its purpose and significance were explained to the patients in detail, and the patients were asked to fill in the informed consent form, telling the patients that they had the right to withdraw from the trial at any time.

Considering the compliance of patients in the survey, this study collected data from patients at three time periods. The baseline data of patients before intervention were collected in stage 1 (T0), stage 2 (T1) was the third time for chemotherapy (21 days as a chemotherapy cycle), and stage 3 (T2) was the sixth time for chemotherapy.

3.2 measures

Primary outcome measures:

3.2.1 Assessment of upper limb edema on the affected side:

using an inelastic flexible ruler, the circumference of the wrist was measured at five locations: flat wrist stripes, 10cm, 20cm, 30cm and 40cm above the wrist stripes. The upper limb could be divided into four truncated cones, and the measurement value was accurate to 0.Lcm. The upper arm volume can be obtained by using the formula, where π=3.14, each h is 10 cm, C1 and C2 are the circumference of the two measuring points immediately adjacent to each other, and then the upper arm volume is obtained by adding up the limb volumes at several locations. According to the International Society of Lymphatics, a volume difference of 10% or more is defined as lymphedema, less than 20% as mild lymphedema, 20% to 40% as moderate lymphedema, and more than 40% as severe lymphedema.

Secondary outcome measures:

3.2.2 Assessment of grip strength of the affected side

The AOPI OpI EH101 electronic grip device was used to detect the grip strength of the affected side. The test method was as follows: the patient stood up straight, the arm was drooped, and the affected hand grasped the grip meter to grasp the grip strength. A total of 2 measurements were performed, and the average value of the two tests was taken and recorded in kg.

3.2.3 Shoulder range of motion measurement

ROM of the upper limb of breast cancer patients was measured with a circular protractor (0°-360°) manufactured by Handan Jiuxu Medical Device Co., LTD. The range of motion of the upper extremity was measured by the rehabilitation technologist in 6 directions: forward flexion, posterior extension, abduction, adduction, internal rotation and external rotation.

3.2.4 Subjective assessment of upper limb dysfunction

The Chinese version of DASH scale, adapted from the DASH scale developed by Beaton, was used to evaluate the upper limb condition of the patients. Cronbach's A coefficient was 0. 911 and intra-group correlation coefficient was 0. 882. The highest score is 100 and the lowest is 0, with higher scores indicating more severe upper arm problems.

3.2.5 Quality of life evaluation of breast cancer patients

The FACT-B 4.0 scale developed by Cella and translated by Wan Chonghua was used to measure the quality of life of patients. The correlation R value between each dimension and the total scale was more than 0.65, and the Cronbach's α of each dimension was 0.61-0.84, which is one of the most commonly used scales to evaluate the quality of life of breast cancer patients. It contains 5 dimensions, a total of 36 items, using a 5-level score, the higher the score, the higher the quality of life of patients.

4 Data analysis

SPSS21.0 software was used, a two-sided test was set, and α was set at 0.05.The normality of measurement data was expressed as mean ± standard deviation (±s), and two independent sample t-test was used. When not normal, the median and interquartile range [M(Q)] were expressed using the Mann-Whitney U test. Enumeration data were expressed as frequency and constituent ratio using 2 test. Mann-whitney U test was used for grade data.

5 RESULTS

In this study, a total of 108 patients completed the baseline survey (T0), 56 in the control group and 52 in the intervention group. A total of 11 patients fell off during the study (6 in the control group and 5 in the intervention group), and a total of 97 patients completed the study (50 in the control group and 47 in the intervention group), as shown in Figure 1.