

The therapeutic response to any treatment provided depends not only on the physiological actions of the treatment but also on the cultural, social, psychological, and physical conditions of each patient. One of these components, which may influence the therapeutic response, is the quality of life. According to the World Health Organization (WHO) quality of life is defined as “individuals’ perception of their position in life in the context of culture, value systems in which they live in relation to their goals, expectations, standards, and concerns [15]. For patients with breast cancer, quality of life assessment will approach the way they experience changes caused by the disease as well as the positive or negative influence that the treatment will have on their lives [16–23].

In this context, this study aims to evaluate QOL as a predictor of treatment response in women undergoing CPT in the treatment of upper limb lymphoedema after axillary lymphadenectomy.

2. Materials and Methods

A randomised clinical trial was conducted in women with secondary treatment of breast cancer lymphoedema. The study methodology has been previously detailed [9].

In order to perform the study, 57 women referred for unilateral axillary dissection, with a difference between the upper limbs greater than three centimeters in circumference at one point at least, who were not undergoing chemotherapy or adjuvant radiotherapy and showed no heart disease or systemic decompensated hypertension, were included. Women were excluded if they had surgery less than six months previously, were diagnosed with preoperative lymphoedema, showed signs of inflammation in the swollen limb, had a history of allergic reaction to the material used for compression bandaging, had active locoregional or distant disease, or had been undergoing treatment for lymphoedema with compression bandaging for the last three months.

For the treatment of lymphoedema, all patients underwent complex physical therapy (skin care, compression bandaging, exercises, and home orientations), with or without manual lymphatic drainage.

The main outcome (therapeutic response) was considered to be the percentage reduction in excess limb volume between the beginning and the end of treatment (end of compressive bandaging, occurring in about 4 weeks), calculated by $(IV - FV/IV) * 100$, with IV being the initial volume and FV the final volume. The estimated volume of the limb (V) was obtained from the circumference. The measures for each point which were used were $V = h * (C^2 + C * c + c^2) / (\pi * 12)$, in which V is the volume of the limb segment, C and c are the circumferences at each end, and h is the distance between the circumferences (C).

Descriptive variables were collected, such as age, body mass index (BMI), time to onset postoperative lymphoedema, excess volume in the segment, duration of chronic lymphoedema, and the number of infections in the limb with lymphoedema.

As the main predictor variable, the mean score of quality of life was considered, measured at study entry. Quality of life was assessed by the EORTC QLQ-C30 and BR23, both validated by the Brazilian population [16]. QLQ-C30 is a multidimensional questionnaire designed to assess the psychological and social functioning of patients with cancer. It is made up of 30 questions that assess five functional scales (physical, functional, cognitive, emotional, and social role), three symptom scales (fatigue, pain, nausea, and vomiting), and quality of life scales and overall health. QLQ-BR23 intends to specifically evaluate the effects of treatment in patients with breast cancer. It consists of 23 questions divided into two scales: physical functioning and symptoms. The functional scale is divided into ranges of body image, sexual function, sexual satisfaction, and future perspective. The second level consists of the subscales: adverse effects of systemic therapy, breast symptoms, and arm symptoms. QLQ-C30 and BR23 have a scale ranging from 0 to 100, in which 0 is the worst health status and 100 the best of health, except for the symptom scales in which higher scores represent more symptoms and worse quality of life. For statistical analysis, the symptom scale was reversed so that higher scores represent better quality of life [15].

The descriptive analysis of the study population was performed by using measures of central tendency and dispersion. To evaluate the changes in excess volume before and after treatment, we performed the Wilcoxon signed-rank test, considered statistically significant at $p < 0.05$. Linear regression was performed to evaluate the association between the scores of the domains of quality of life before treatment and the therapeutic response. The statistical package SPSS 20.0 was used for all analyses.

The project was approved by the Ethics Committee in Research of the National Cancer Institute (INCA) under registration number 011/07 and was in accordance with the Helsinki Declaration of 1975, as revised in 2008. All participants signed the informed consent form.

3. Results

The study included 57 women. At inclusion in the study, the average age of the study population was 63 years (SD 10.02), mostly overweight and obese. The average time after surgery until the development of lymphoedema was 37 months. At the beginning of treatment, lymphoedema was present for a median of 61 months (5 years). At baseline, the mean excess volume (EV) between the upper limbs was 776.16 mL, corresponding to a percentage excess volume (PEV) of 44.2% (Table 1).

After treatment, the absolute decrease in statistically significant excess volume between the upper limbs of 282 mL was observed, representing a reduction of 15% ($p = 0.001$) (Table 2).

In measuring quality of life for the functional scale of the EORTC QLQ-C30 questionnaire, the worst scores for emotional function (55 points) and better social function (89 points) were observed. In the symptom scales, pain presented the worst average (66 points), followed by fatigue