Use of Saint Germain flower combined with tamoxifen changes IL-6 levels in women with breast cancer

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1 INTRODUCTION

Breast cancer (BC) is the second most incident malignant neoplasm in the world, with a high prevalence in females, with high severity and biopsychosocial impact. Of multifactorial origin, BC is the first cause of female death in Brazil, in addition to presenting a high morbidity, whose treatment, whether surgical or pharmacological, generates several undesirable effects, both physical and psychological. The use of evidence-based integrative therapies aims to contribute to conventional treatment by reducing the symptoms of the disease, reducing the adverse effects of treatments and increasing the quality of life of patients. Association of Complementary Integrative Practices (PICS), through the application of Saint Germain Flowers, aims to contribute to the reduction of pro-inflammatory molecules, acting as an adjuvant in mitigating the negative effects generated by the different treatments.

2 OBJECTIVE

To investigate the therapeutic effects of Saint Germain florals on the profile of the inflammatory marker IL-6 in women affected by breast cancer using tamoxifen.

3 METHODOLOGY

This study was approved by the Human Research Ethics Committee under the registration numbers 3.631.764 and 4.020.758. This is a pilot, randomized, double-blind clinical trial using a known oral dose of floral in the intervention group regardless of the weight of the patients and the same dose without the floral in the placebo group, being female patients, over 18 years old, affected by breast cancer and who were using tamoxifen and accepted to participate in the study. The follow-up of the patients was six months, with a collection of blood and serum samples for the dosage of the

inflammatory marker IL-6 before the use of the floral or placebo and a collection six months later, by the ELISA colorimetric method, with the first collections being initiated in the year 2019-2020.

4 DEVELOPMENT

In this study, 42 women participated, and at the end of six months, 30 women completed this stage of the study (pre and post use of the Floral). The group with floral use presented mean serum levels of IL-6 significantly lower than the placebo group ($p > 0.005$) after six months of placebo or floral use segment, demonstrating a decrease in the inflammatory action of this marker in patients who used the floral. It is worth mentioning that, as expected in cancer patients, both the placebo group and the group that used the florals had high levels of the inflammatory marker IL-6, when we evaluated the average levels in non-tumor patients compared to data present in the literature. IL-6 is a pro-inflammatory cytokine that is involved in the regulation of immunological, inflammatory and hematopoiesis processes (SANGUINETTI et al, 2015; SUN et al., 2019), being one of the main inflammation-inducing molecules acting in chronic diseases and in the tumor microenvironment (KAMPAN et al., 2018). Additionally, IL-6 plays a key role in tumor evolution, where its high levels are related to advanced tumor stages and therapeutic resistance in tumor cell proliferation and survival, migration, invasion, angiogenesis and resistance to chemotherapy (KUMARI et al., 2016), being associated with aggressive tumor phenotypes and poor survival in patients in different tumor types, including breast cancer (AHMAD et al., 2018).

5 FINAL CONSIDERATIONS

The use of *St. Germain* flower blossoms can modulate inflammatory processes and influence immune responses in patients with CM, by reducing IL-6 levels combined with conventional treatment, improving the quality of life of patients. In addition, decreases in inflammatory processes may help reduce adverse effects due to conventional treatments. The measurement of plasma cytokine concentration in women with cancer is a less invasive and indirect way to evaluate the systemic inflammatory/regulatory response and the role of the microenvironment formed in the pro- and anti-inflammatory response of the host. Furthermore, the study of biomarkers of inflammation may provide greater insight into the biological behavior of these tumors as well as signal for future biomarkers of disease activity and their therapeutic monitoring.

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