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STUDY PROTOCOL FOR ORAL CHEMOTHERAPY ADHERENCE: A NON-EXPERIMENTAL STUDY INVESTIGATING ADHERENCE TO MEDICATION IN GREEK CANCER PATIENTS

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ABSTRACT

Background: The use of oral antineoplastic agents has become very popular due to the enormous progress in cancer treatment. As the use of oral antineoplastic treatment increases, the problem of non-adherence with treatment also appears to rise significantly. While a large number of studies have focused on the investigation of treatment compliance, only a small number have referred to oral chemotherapy or targeted therapy. The purpose of this study is to assess the adherence to medication in cancer patients undergoing oral chemotherapy and to determine the factors affecting patients' adherence. **Methods:** This will be a descriptive and non-experimental study. The sample will consist of patients with different types of cancer who are receiving oral chemotherapy. The questionnaire that will be used is the Oral Chemotherapy Adherence Scale (OCAS). The data collection will be conducted at oncology hospitals in Athens and Thessaloniki and in general hospitals in Greece that have oncology departments. Initially, a pilot study will be carried out to investigate the patients' understanding of the questionnaire. The data analysis will be performed using the statistical software package SPSS 21.0 for Windows. A descriptive analysis will be conducted for all variables, and parametric or non-parametric tests will be employed, depending on the normal distribution of the data. **Discussion:** We expect variability in adherence among the participants. The evaluation of the adherence may be varied by type of tumour, the stage of cancer, and other clinical or demographic characteristics of patients. We expect that this study will provide valuable knowledge that will be useful for healthcare professionals, especially nurses. The results will be extremely significant for Greek nurses towards assessing the adherence in clinical and community settings and planning interventions to enhance the adherence to oral chemotherapy.

KEYWORDS: Adherence, oral chemotherapy, cancer.

INTRODUCTION

Cancer is among the primary causes of death worldwide. In 2017, there were an estimated 1,688,780 new cancer cases diagnosed and 600,920 cancer deaths.[1] Each year in Europe, there will be 3.2 million new cases and 1.7 million deaths.[2] In Greece, cancer is the second primary cause of death after cardiovascular diseases.[3] The treatment of cancer includes surgical treatment, chemotherapy, radiotherapy, hormone therapy, immunotherapy, and targeted therapy.[1] Nowadays, the use of oral antineoplastic agents has become very popular owing to the enormous progress in cancer treatment.[4] As the use of oral antineoplastic treatment increases,[5] the problem of non-adherence with treatment also appears to rise significantly.[4]

According to the World Health Organization (WHO), adherence is defined as 'the extent to which the patient follows medical instructions'.[6] Recently, the International Society for Pharmacoeconomics and Outcome Research (ISPOR) defined adherence as synonymous with compliance as 'the degree or extent of conformity to the recommendations about day-to-day treatment by the provider with respect to the timing, dosage, and frequency'.[5] Compliance of cancer patients varies from 16-100%, depending on the different treatments and assessing methods.[5]

BACKGROUND

A large number of studies are focused not only on the investigation of treatment compliance (mainly in women with breast cancer undergoing hormone therapy) but also

on investigating the factors contributing to non-compliance. It should be noted that there are a small number of studies that refer to oral chemotherapy or targeted therapy. Below are the results from the literature review.

Brito et al (2014), in a retrospective study, investigated 5,671 women who had breast cancer and received hormone therapy. A system for calculating the pills was used to assess compliance. The adherence rate was 76.3%, and the likelihood of increased adherence with treatment increased with each additional treatment period, the level of education, them having/not having a partner, them having had surgery, and the specialty of the doctors who advised them. Conformance levels were small in end-stage patients, in those who consumed alcohol, in those undergoing chemotherapy, in those who had performed more diagnostic tests, in those who had increased home care, and in those who were treated with tamoxifen.[7]

In a qualitative study conducted by Harrow et al. (2014), 80 women with breast cancer who had received hormone therapy for 1-5 years were investigated on their perceptions about the purpose of medication and the side effects of treatment. Patients mentioned that they would like to receive hormone therapy because they believed it offered more protection against breast cancer. Although some women endured a range of side effects due to the hormone therapy, they did not stop taking their medication as it had had a tremendous impact on the quality of their life.[8]

Boons et al (2014) described a multicentre prospective observational cohort study that will investigate 70 adult patients with chronic phase-chronic myelogenous leukaemia (CP-CML). These patients will start treatment with nilotinib, which will be followed up for at least 12 months. Response to treatment will be evaluated after 3, 6 and 12 months. The study also aims to identify possible predictors for response to nilotinib treatment and included adherence, occurrence of side effects, and so on among the hypothesized predictors. The estimation of oral chemotherapy adherence will be performed by measuring the pills while, at the same time, assessing the red blood cell levels, the drug levels in the plasma, the patient's reported side effects, and the patient behaviour. The behaviour will be assessed by employing Medicare Adherence Rating Scale, Quality of Life with the SF-12 scale, and patients' attitude towards the illness and the medication using the Brief Illness Perception Questionnaire (IPQ) and Beliefs on Medicines Questionnaire (BMQ).[9] Hershman et al. (2010) studied treatment discontinuation and adherence in 8,769 women with stage I–IIIC breast cancer undergoing hormonal therapy, such as tamoxifen, aromatase inhibitors, or both. The factors associated with treatment discontinuation include age, type of surgery, and co-morbidities. Other factors such as race, marital status, and type of treatment (chemotherapy or radiotherapy) are related to the continuation of the treatment.[10]

In another study, Cowley et al. (2014) identified barriers to the compliance in 113 women with Stage I breast cancer. 64% percent were compliant, and 36% were noncompliant. They identified ten reasons for delayed compliance, including patient- and system-level barriers. More than half the patients (56%) had more than one reason contributing to delay.[11]

In Italy, a study was conducted by Rivasi et al. (2013) in which 326 patients were treated with anastrozole, letrozole, hexamenestase, or tamoxifen. The results showed that 46% of the patients showed poor/mild compliance, 20% showed good compliance, and only 34% showed excellent compliance. The researchers concluded that more interventions were required to improve patient compliance throughout the course of treatment.[12]

Ruddy et al. (2012) studied persistence to adjuvant therapy with cyclophosphamide-methotrexate-5-fluorouracil (CMF), adherence to oral cyclophosphamide, and the association of these with toxic effects in 133 breast cancer patients. They found that 5% persisted with adjuvant therapy and that the average adherence was 97% during the prescribed cycles. Non-persistence was associated with node negativity, febrile neutropenia, and fatigue.[13] In patients with prostate cancer who received both Abiraterone acetate and prednisone, adherence was found to be 90% high among all age groups.[14]

Other studies have investigated factors that affect adherence. Some of these are age, side effects,[15] sociodemographic factors, types of drugs,[16] educational level, economic factors, and factors related to the health professional.[17,18]

In conclusion, the literature review reveals that most of the studies concerned the adherence of women with breast cancer undergoing hormone therapy, and few studies are available about adherence to oral chemotherapy. Although the body of evidence is expanding with respect to the latter, little is known about this issue in Greece. Greek nurses show an increasing interest for patterns of adherence during chemotherapy, but this issue remains unrecognized in clinical practice. The purpose of this study was to assess adherence to medication in cancer patients undergoing oral chemotherapy and to determine the factors affecting patients' adherence.

METHODOLOGY

Sample

A descriptive and non-experimental study will be employed for this research. The sample will be constituted by patients with different types of cancer receiving oral chemotherapy. The inclusion criteria for

the patient's entry into the study will as follows: a) histological diagnosis of cancer; b) oral intake of at least one chemotherapeutic drug; c) receiving chemotherapy for at least 3 months; d) >18 years old; e) knowledge of the Greek language. Patients receiving concomitant chemotherapy and radiotherapy will be excluded from the study.

Instruments

For this study, the most appropriate questionnaire according to the literature will be used. The questionnaire that has been chosen is the Oral Chemotherapy Adherence Scale (OCAS). This scale comprises 19 sentences, each of which is rated in a five-point Likert from 1–5, where 1 corresponds to 'never' and 5 to 'always'. It can be used even in the case of patients who have taken just one oral chemotherapy drug. The total scores are used to evaluate the scores obtained from the scale; a score of 84 and higher is considered "good adherence" and 83 and lower as "bad adherence". The scale is subdivided into 3 sub-scales: the first is called 'expected' behaviour during treatment; the second refers to the 'barriers', and the third is called 'expected behaviours during drug usage'.[19,20] In previous studies, it was proved that the OCAS has acceptable psychometric properties and is appropriate for use in research.

Data collection

The data collection will be conducted at oncology hospitals in Athens and Thessaloniki and in those general hospitals in Greece that have oncology departments. Initially, a pilot study will be performed to investigate patients' understanding of the questionnaire. It will be possible to modify the questionnaire. The hospital's research committee has provided its approval for the study. All potential participants who meet the inclusion criteria will be approached by a member of a research team and introduced to the aim of the study. A confidential letter will be distributed to these potential participants to inform them about the study and the rights of the participants. Confidential statements were then collected from the patients who agreed to participate, and they were then given the questionnaire.

Data analysis

The data analysis will be performed using the statistical software package SPSS 21.0 for Windows. A descriptive analysis will be carried out for all variables. Mean and standard deviation will be utilized for quantitative variables that follow a normal distribution. For the rest of the variables, the median, the maximum, and the minimum values will be used. Parametric or non-parametric tests will be used depending on the normal distribution of the data. All p-values reported are two-tailed, and the statistical significance is set at 0.05.

DISCUSSION

The present study will be conducted to evaluate the adherence to treatment in cancer patients and the factors that affect it, and variability in adherence is expected among the participants. The evaluation of the adherence may be varied by type of tumour, the stage of cancer, and other clinical or demographic characteristics of patients. To obtain greater insight into factors related to the adherence of treatment, the possible factors that affect it will be studied in an explorative manner. As a result, the examination of these factors will provide a broad insight into the use of oral chemotherapy among cancer patients in Greece. To date, no study in Greece has examined this adherence and the factors that influence it in cancer patients who take oral chemotherapy. We expect that this study will provide valuable knowledge that will be useful for health care professionals and nurses especially. The results will be very significant for Greek nurses towards recognizing and assessing the adherence in clinical and community settings. Recognition and evaluation of this by nurses can lead to increased continuity in nursing care and planned interventions to enhance the adherence to oral chemotherapy.

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