RANDOMIZED STUDY OF ADVERSE EVENTS TO CAPECITABINE IN PATIENTS WITH COLON AND RECTUM CANCER

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Introduction

Therapeutic options for treating colorectal cancer depend on the patient's staging and clinical condition [1]. Among these, capecitabine alone or in combination with oxaliplatin or radiotherapy is an option [2,3]. Capecitabine is an oral antineoplastic that can provide a better quality of life for the patient. However, toxicity in incorrect handling and storage of the medication, late detection of adverse events (AE) and non-adherence are among the risks associated with this therapy[4] . The preventability of some adverse reactions (AR) is related to the identification of adverse events [5]. The recurrence and severity of AR can directly interfere with the patient's quality of life and their tolerability to [6]. The research aimed to identify and classify adverse events to capecitabine, in addition to evaluating their clinical impact on the treatment of patients with colon and rectal cancer.

Material and Methods

A randomized clinical trial was carried out with patients using capecitabine between April 2022 and July 2023 in an oncology reference hospital in the city of Rio de Janeiro. These were grouped into an intervention group (IG), with full pharmaceutical care provided, and a control group (CG), which only received standard dispensing of the medication. AEs in the IG were identified through pharmaceutical consultation and data obtained from medical records, while the CG were identified only through analysis of medical records. These were identified and classified according to causality and severity [7,8] . The clinical impact was assessed by dose reduction, temporary and/or definitive suspension of capecitabine. Statistical analysis was conducted using the Shapiro – Wilk test and then the Mann-Whitney, Fisher and Chi-square tests, using the BioEstat v.5.0 program. The project was approved under number 53553221.9.3001.5274 by the institution's Research Ethics Committee.

Results and Discussion

The majority of patients (CG:83.3%; GI:91.7%; p=0.666) presented some AE, such as nausea (CG:45.8%; GI:62.5%; p=0.384), diarrhea (CG:33.3%; GI:62.5%; p=0.083) and Hand Foot Syndrome (CG:33.3%; GI:41.7%; p=0.765). These data corroborate studies available in the literature, with gastrointestinal disorders and skin toxicity among the most common AEs associated with capecitabine [9,10] . Regarding severity, regardless of the group, 83.1% of AEs (CG:71.4%; IG:91.7%; p=0.061) were classified as mild (grades 1 and 2) [11]. Of the AEs, 75.7% (CG:74.1%; IG:76.7%; p=0.787) had no clinical occurrence, which can be justified by the majority of these being mild in severity. However, capecitabine discontinuation was observed in 15.6% (CG: 17.3%; IG: 14.3%, p=0.634) of AE cases. Regarding causality, the majority of events (99.5%; CG: 100.0%; GI: 99.2%; p= 1.000) were classified as possible adverse reactions to capecitabine. More AEs were identified in the intervention group (CG: 39.0%; IG: 61.0%), which had a statistically significant difference (p= 0.041) when compared to the control group. The discrepancy between the groups can be justified by the presence of the pharmacist, in order to assist in the detection of AEs, thus the result of the control group may be the product of underreporting.

Conclusion

The results demonstrate the importance of pharmaceutical care in the early detection of AEs associated with capecitabine. Early management of AEs reduced their worsening, as well as the likelihood of dose reduction or treatment suspension, thus improving the patient's quality of life.

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