CLINICAL TOXICITIES IN PATIENTS RECEIVING A 5-FLUOROURACIL-BASED PROTOCOL FOR GASTROINTESTINAL CANCER TREATMENT

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Introduction: 5-Fluorouracil (5-FU) is an essential therapeutic agent in the treatment of gastrointestinal tract (GI) cancers, forming the basis of various clinical regimens. The FOLFOX protocol (5-FU + leucovorin + oxaliplatin) is widely used, particularly as adjuvant therapy for metastatic colorectal cancer. Approximately 10–30% of patients receiving 5-FU monotherapy develop severe toxicities, with 0.5–1% resulting in death. Toxicity may be intensified when 5-FU is combined with other cytotoxic agents such as oxaliplatin in the FOLFOX regimen. This study aimed to identify clinical toxicities in cancer patients treated for GI cancers at the University Hospital of Santa Maria using a 5-FU-containing regimen. **Material and Methods:** The toxicities of the cancer patients evaluated in this study were assessed and graded using the Common Terminology Criteria for Adverse Events (CTCAE), version 5.0, based on the clinical signs and symptoms presented. Clinical data were collected from patients' medical records. The study was approved by the UFSM Ethics Committee (CAAE No. 44256821.5.0000.5346). **Results:** Forty patients were included in the study, all diagnosed with GI tract cancer and treated with the FOLFOX protocol. The mean age was 64.68 ± 11.21 years. Most patients were men (72.5%) and women accounted for 27.5%. The most common type of cancer was colon cancer (27.5%). Reported toxicities included Grade III diarrhea in 2.5% of patients after the first cycle and Grade I mucositis in 2.5%. No cases of neurotoxicity, hand-foot syndrome, or cardiotoxicity were observed. **Conclusion:** Although no Grade IV clinical toxicities were observed, it is crucial to emphasize the importance of patient monitoring since the first treatment cycle, as toxicities may emerge early, as shown in our results. Monitoring these events, as conducted in our study, is essential to ensure early and safe intervention. In Brazil, no antidote is approved for 5-FU-related toxicities; only supportive care is available. Although only mild toxicities or those resolved with minimal interventions (Grade III) were observed in our cohort, in cases of severe intoxication, the absence of specific treatment options may increase the risk of death.

Keywords: 5-FU, Chemoterapy protocols, FOLFOX regimen, Adverse effects, Toxicology

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