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Evaluation of the safety profile of adjuvant treatment of colon cancer in patients with concomitant type II diabetes.

Abstract

The colon is the part of digestive tract where cancer is most often located. Epidemiological data prove that this disease is a growing problem of modern medicine. The method of treatment depends on many factors and results mainly from the stage of the disease. The most important risk factor for colorectal cancer is age over 40. This factor causes that colorectal cancer often coexists with other diseases, including diabetes. Systemic changes caused by diabetes not only increase the likelihood of colorectal cancer, but also probably affect the clinical course of cancer, thus affecting the efficacy and safety profile of the treatment.

The aim of research was to assess the safety profile of patients with type II diabetes mellitus who underwent adjuvant chemotherapy for colon cancer, and thus tried to answer the question whether diabetes coexistence should be a factor influencing the choice of treatment strategy after surgery.

Material and methods

The study population consisted of a total of 102 patients undergoing adjuvant chemotherapy for colon cancer. The study population was divided into two groups. The first was the study group, consisting of 52 patients, the second was the control group, consisting of 50 people. Type II diabetes was the criterion of division. The study covered the time from surgery to the end of adjuvant treatment and was based on a retrospective collection of patient data. The data included: type of surgery, stage of advancement according to TNM, results of laboratory tests, performance status according to the Zubrod scale, selected treatment regimen, percentage of drug doses administered in relation to maximum doses, side effects and reasons for delaying the supply of subsequent cycles. The second part of the

study was the statistical analysis of the obtained data. The third part of the study was the rough set analysis.

Results

The number of chemotherapy cycles in diabetic patients was significantly lower than the number of chemotherapy cycles in non-diabetic patients. Patients with diabetes statistically significantly more often terminated treatment before the planned time, or the intervals between individual cycles were so extended that within the planned six-month period it was not possible to implement the originally planned treatment plan.

In the study group, the percentage of dose compliance for both fluoropyrimidines and oxaliplatin was lower, and the analyzed difference for fluoropyrimidines reached the level of statistical significance. Assessing the effect of chemotherapy on haematological toxicity, the study showed that diabetes is an independent predictor of the chance of thrombocytopenia. This relationship has not been proven for the risk of neutropenia or anemia.

The polyneuropathy complication mainly concerned patients treated with oxaliplatin-containing regimens, and gender analysis showed that women are at higher risk of developing polyneuropathy. The analysis of the impact of diabetes showed a higher incidence of polyneuropathy symptoms in the study group compared to the control group. CIPN, if present, was reported earlier among people with concomitant diabetes. It was also shown that polyneuropathy is more common in the study group of greater intensity.

The study showed that the method of rough set analysis used to assess the safety profile of pharmacotherapy can be a source of valuable data, which do not always clearly correlate with the results obtained using statistical methods. Non-statistical analysis highlighted the importance of thrombocytopenia as a factor in the safety profile of diabetic patients in the adjuvant treatment of colon cancer.

Conclusions

1. Diabetic patients more often end treatment without reaching the planned stage and receive a lower total dose of anticancer drugs compared to non-diabetic patients.
2. In the group of diabetic patients, the occurrence of side effects was more frequent, resulting in the need to change treatment regimens and/or to discontinue chemotherapy.

3. Diabetes is a factor intensifying the occurrence of thrombocytopenia as a haematological complication of adjuvant chemotherapy for colon cancer.
4. Polyneuropathy occurs more frequently and is more severe in the group of patients with concomitant diabetes.
5. The choice of an oxaliplatin-based regimen in patients with diabetes seems to be a factor that additionally increases the likelihood of complications in patients undergoing adjuvant treatment in the course of colon cancer.
6. Rough set analysis of the assessment of the pharmacotherapy safety profile may be a source of valuable data, which are not always unambiguously correlated with the results obtained using statistical methods.

Key words: pharmacovigilance, colon cancer, adjuvant chemotherapy, chemotherapy, diabetes.