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Modern Diagnostics of the Impact of Cardiovascular Diseases on the Stomach

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Annotation: As a result of the studies, no bleeding or adverse effects on the cardiovascular system (recurrent myocardial infarction, stroke, etc.) were observed during treatment with Controloc. The drug was well tolerated in almost all patients. Complications of erosive and ulcerative lesions of the gastrointestinal mucosa, such as bleeding, were absent in all patients.

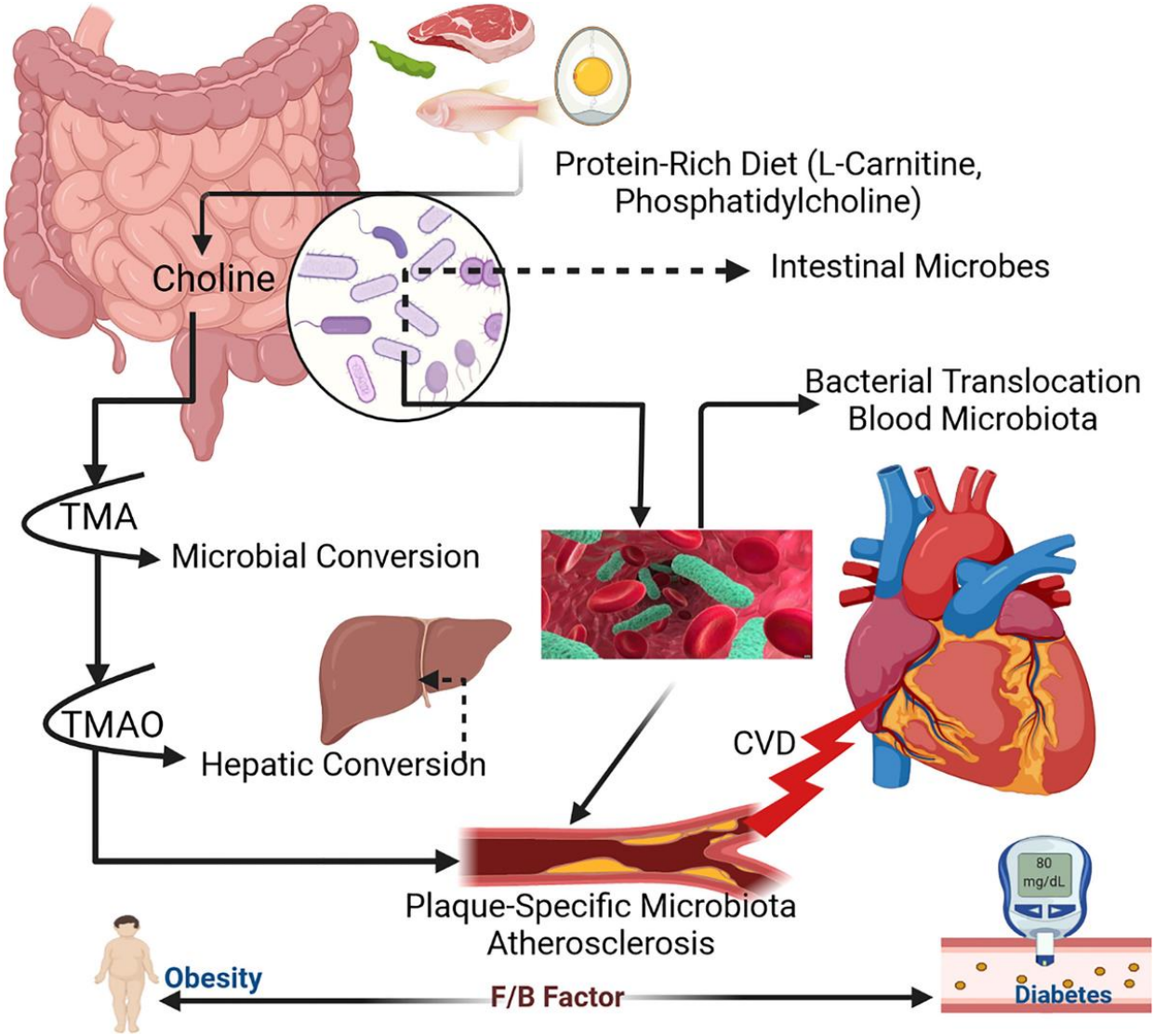
Keywords: cardiovascular diseases, blood loss, bleeding, gastrointestinal tract, stomach diseases, stomach ulcers, anticoagulant therapy, antiplatelet therapy, gastroenterology.

Introduction

Patients with cardiovascular diseases in some cases require long-term or continuous therapy with antiplatelet and / or anticoagulant drugs, which increase survival and are an integral part of complex therapy and prevention of various diseases of the cardiovascular system. However, these drugs have a number of side effects. The most common are erosive and ulcerative lesions of the gastric mucosa, bleeding and bleeding from the upper gastrointestinal tract (GIT). The risk of such complications increases significantly with concomitant treatment with drugs such as non-steroidal anti-inflammatory drugs, corticosteroids, anticoagulants. The combination of acetylsalicylic acid (ASA) and / or clopidogrel with anticoagulants (unfractionated heparin, low molecular weight heparins, warfarin) is accompanied by a significant increase in the risk of hemorrhagic complications, most of which are associated with bleeding from the upper gastrointestinal tract. 2].

Prevention of gastrointestinal side effects is important in the treatment of patients with cardiovascular diseases. Proton pump inhibitors (PPIs) are the drugs of choice for the treatment and prevention of gastrointestinal complications caused by antiplatelet and/or anticoagulant

therapy. PPI therapy has been shown to reduce the incidence of rebleeding and mortality in high and low-risk groups. There is evidence that the simultaneous use of PPIs and antiplatelet drugs leads to a significant decrease in the effect of the latter. The possibility of reducing the effectiveness of clopidogrel in patients taking PPIs was first shown by M. Gilard et al. in 2008 [3].



In 2009, DN Juurlink et al. found that PPI therapy other than pantoprazole in patients receiving clopidogrel after acute myocardial infarction was associated with a decrease in the beneficial effect of clopidogrel and an increased risk of recurrent infarction [4]. The emergence of these data led to numerous studies - population-based and clinical. In a comparative study of different PPIs, it was found that pantoprazole is metabolized by cytochrome P450 2C9, therefore, unlike other PPIs, it does not affect the metabolic activity of clopidogrel (N. David et al., 2007). Most PPIs are metabolized by the cytochrome P450 2C19 system (which also metabolizes clopidogrel) and are able to inhibit the bioactivation of clopidogrel and its conversion to the active metabolite. The clinical significance of the identified drug interactions remains highly controversial. Thus, in addition to the above data on the negative effect of PPIs on the efficacy of clopidogrel, there is currently other data that does not confirm the existence of such an effect.

A population-based study of 13,000 patients found no association between PPI use and the risk of recurrent myocardial infarction or death from cardiovascular disease (CVD); these results were independent of the PPI used: omeprazole, rabeprazole, esomeprazole, lansoprazole, or pantoprazole [7, 8]. In another study, the incidence of readmissions for fatal or nonfatal myocardial infarction during a one-year follow-up was similar in patients who took omeprazole and those who did not [9]. Thus, the question of drug interactions (PPI - clopidogrel/anticoagulants) and the

optimal management of patients in a large population of patients with cardiovascular disease who require PPI prophylaxis remains unresolved.

Current recommendations suggest the need for prophylactic use of PPIs in patients with two or more risk factors for bleeding. These factors include: history of gastrointestinal bleeding, older age, concomitant use (in addition to clopidogrel) of warfarin, steroids, nonsteroidal anti-inflammatory drugs (NSAIDs) including aspirin, and Helicobacter pylori infection (HP infection) [10]. The set of risk factors for bleeding is based on available data from controlled clinical trials and may be further expanded and refined. The presence of erosive and ulcerative lesions of the upper gastrointestinal tract may also be a risk factor for bleeding in such patients. Research data indicate the need for further search for PPIs with the best safety profile and for evaluation of their prophylactic efficacy in patients at risk. Currently, the available data on the effect of different PPIs on the effectiveness of antiplatelet/anticoagulant therapy are insufficient to give preference to any drugs. However, according to the available literature, pantoprazole is considered optimal in terms of PPI safety.

Research goals and objectives

The aim of the study was to evaluate the efficacy, tolerability and safety of Controloc 40 mg/day for 3 months for the prevention of bleeding in 30 patients with cardiovascular disease and antiplatelet therapy. / or anticoagulant drugs and having two or more risk factors for the development of bleeding. The objectives of the study included:

To determine the frequency of healing of erosive and ulcerative lesions 1 and 3 months after oral administration of Controloc at a dose of 40 mg per day in 30 patients.

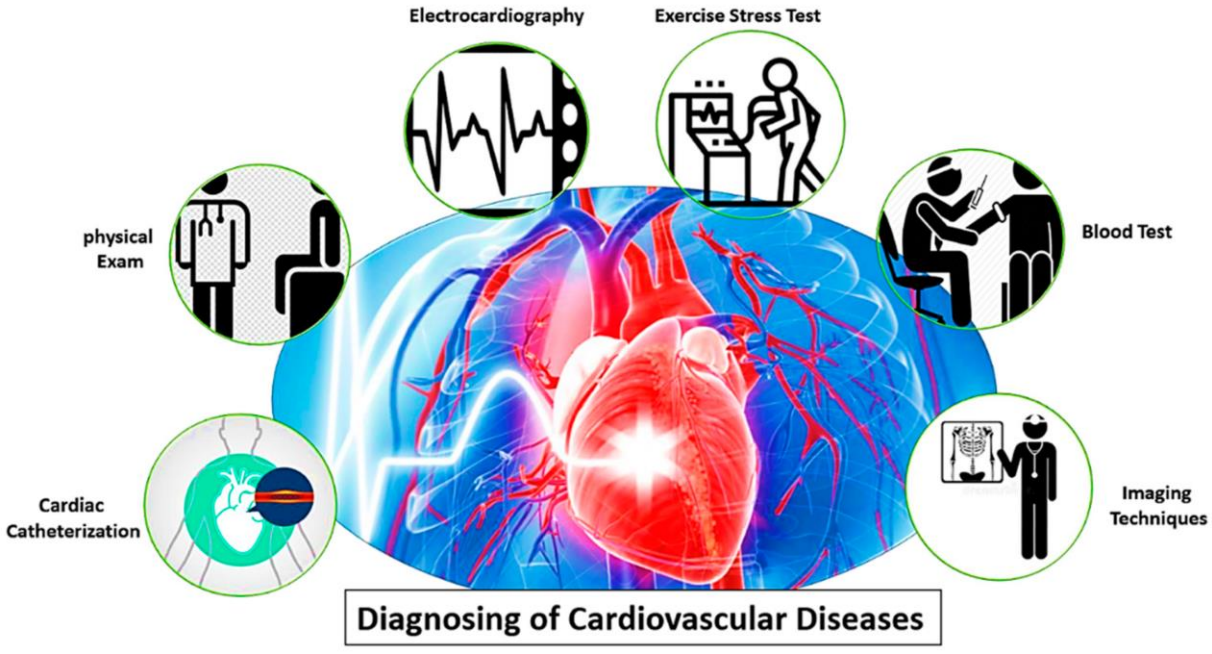
Study the frequency of events:

Bleeding during treatment with Controloc;

Adverse cardiovascular events (recurrent myocardial infarction, stroke, etc.) during treatment with Controloc.

Study tolerance and possible side effects (clinical and laboratory) during treatment with Controloc.

Patients who met the inclusion criteria and did not meet the exclusion criteria were included in the study.



Criteria for inclusion of patients in the study:

a. Patients of both sexes, aged 18 to 75 years;

b. cardiovascular diseases requiring long-term use of antiplatelet and/or anticoagulant agents;

c. erosive and ulcerative lesions of the upper gastrointestinal tract in the acute stage;

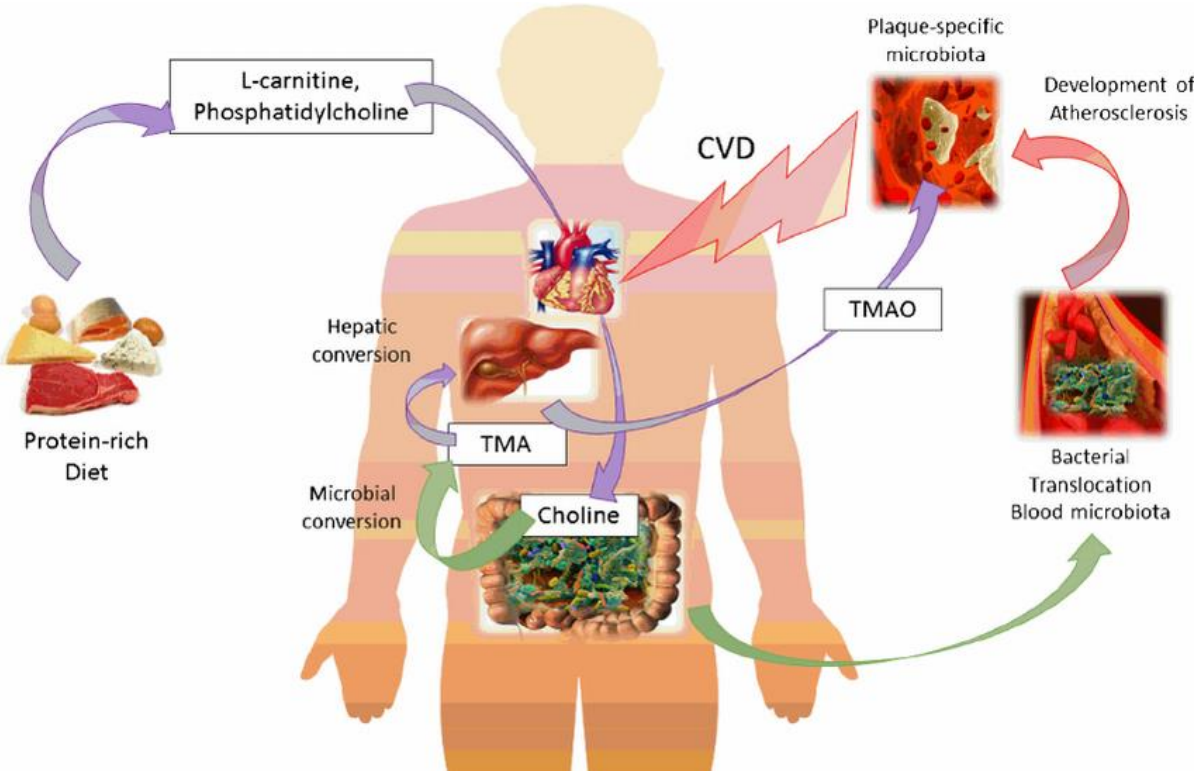
d. the presence of two or more risk factors for bleeding (history of gastrointestinal bleeding; older age; concomitant use of warfarin, steroids, NSAIDs (including aspirin) (except for taking clopidogrel), HP infection).

e. Criteria for excluding patients from the study:

f. the presence of severe renal and hepatic insufficiency;

g. intolerance to pantoprazole;

h. pregnancy or lactation.



Examination and treatment schedule

Controloc was prescribed orally for 3 months at a standard dose of 20 mg 2 times a day. No other PPIs were allowed during the study period. Antiplatelet and/or anticoagulant drugs were taken as prescribed by a cardiologist. The diagnosis of erosive and ulcerative lesions was confirmed endoscopically before the appointment of therapy. Control endoscopic examinations were performed after 1 and 3 months of treatment. General and biochemical (bilirubin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyl transpeptidase (gamma-GT), alkaline phosphatase (ALP)) blood tests and coagulograms were performed before and after the end of treatment with Controloc. studied.

Excellent efficacy: Treatment with Controloc resulted in complete healing of erosive and ulcerative lesions after 1 month of therapy and did not cause complications/adverse reactions.

Good efficacy: Treatment with Controloc resulted in complete healing of erosive and ulcerative lesions after 3 months of therapy and did not cause complications/adverse reactions.

Satisfactory efficacy: healing of erosive and ulcerative lesions was not noted at month 3, but

bleeding did not develop.

Low efficacy: development of bleeding; presence of side effects that do not allow continuing treatment with Controloc.

The criteria for the effectiveness of therapy were the following parameters:

There is no bleeding during treatment.

Frequency of healing of erosive and ulcerative lesions during treatment with Controloc after 1 and 3 months of treatment.

The overall safety of therapy was assessed by collecting reports of adverse events and changes in vital signs (heart rate and blood pressure, respiratory rate), and by evaluating objective and laboratory data (complete and biochemical blood tests, coagulograms). The safety indicator was the frequency of adverse events assessed during the study. An adverse event was defined as any untoward symptom or condition that occurred in a patient participating in a clinical trial and that was not necessarily causally related to the study drug. The tolerability of the drug was assessed as follows:

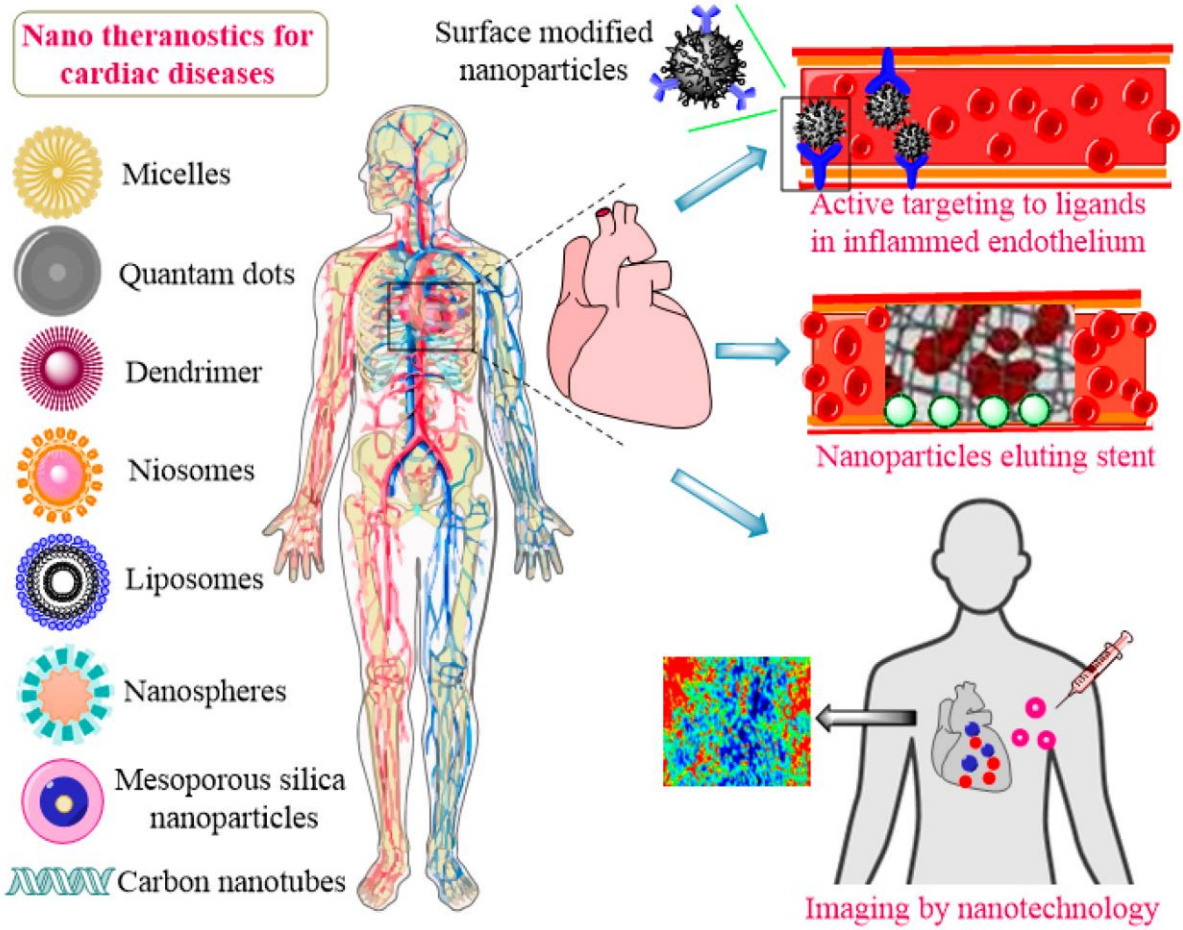
Excellent tolerance: no side effects.

Well tolerated: the development of mild side effects that do not require discontinuation of therapy.

Satisfactory tolerability: the development of moderate side effects that require a reduction in the dose of the drug.

Poor tolerability: development of serious side effects requiring discontinuation of treatment.

Statistical processing of clinical, laboratory and instrumental research data was carried out using the standard Statistica 6.0 software package using the Student's t test and the methods of variance statistics.



Research results

The study included 30 patients: 19 men and 11 women. The average age was 62.8 ± 7.9 years. All patients had cardiovascular diseases in various combinations (Table 1). Drug therapy for cardiovascular diseases that could lead to the development of upper gastrointestinal bleeding is presented in Table 2. All studied patients had complaints from the cardiovascular system (Table 3). Treatment of cardiovascular diseases was effective in almost all patients: by the 3rd month of treatment, the symptoms completely (76.7%) or partially (23.3%) disappeared, and no patient showed negative dynamics. Complaints from the gastrointestinal tract in the studied patients were mild, and the most disturbing were heaviness, discomfort, and heaviness in the epigastric region (Table 4).

After 1 month of treatment, all clinical manifestations were resolved in all patients. The dynamics of general and biochemical blood test parameters, as well as coagulogram parameters, are presented in Tables 5-7. As can be seen from the presented data, no changes were observed in the clinical and biochemical blood test parameters during the study. In patients who did not receive warfarin therapy, coagulogram parameters did not change during treatment (Table 6). Five patients began taking warfarin after the healing of erosive and ulcerative lesions, that is, after 1 month of therapy with Controloc. At the same time, a natural and significant decrease in the prothrombin index (PTI) and an increase in prothrombin time (PT) and international normalized ratio (INR) were observed (Table 7). The results of endoscopic examination before and after treatment with Controloc are presented in Table 8.

After 1 month of treatment with Controloc, all patients had complete healing of gastric and duodenal ulcers and healing of esophageal erosions; healing of gastric erosions in 82.1% of cases. After 3 months of treatment, complete disappearance of erosions was observed in 96.7% of cases. After 3 months of therapy, only 1 patient had erosive changes in the stomach. After 1 month of treatment with Controloc, this patient was diagnosed with pancreatic cystadenocarcinoma and chemotherapy was started, which caused the ineffectiveness of therapy.

Side effects

After 3 months of treatment with Controloc, a case of persistent gastric erosion (n = 1) was classified as a serious adverse event not related to the study drug. Regarding other adverse events, 1 patient experienced mild dizziness with blurred vision, coinciding with the start of the drug, which did not require dose reduction or discontinuation of the drug and concomitant treatment. It was assessed as possible interaction with the study drug. By the end of the 3rd month of therapy, this disorder resolved spontaneously; Outcome: recovery without sequelae

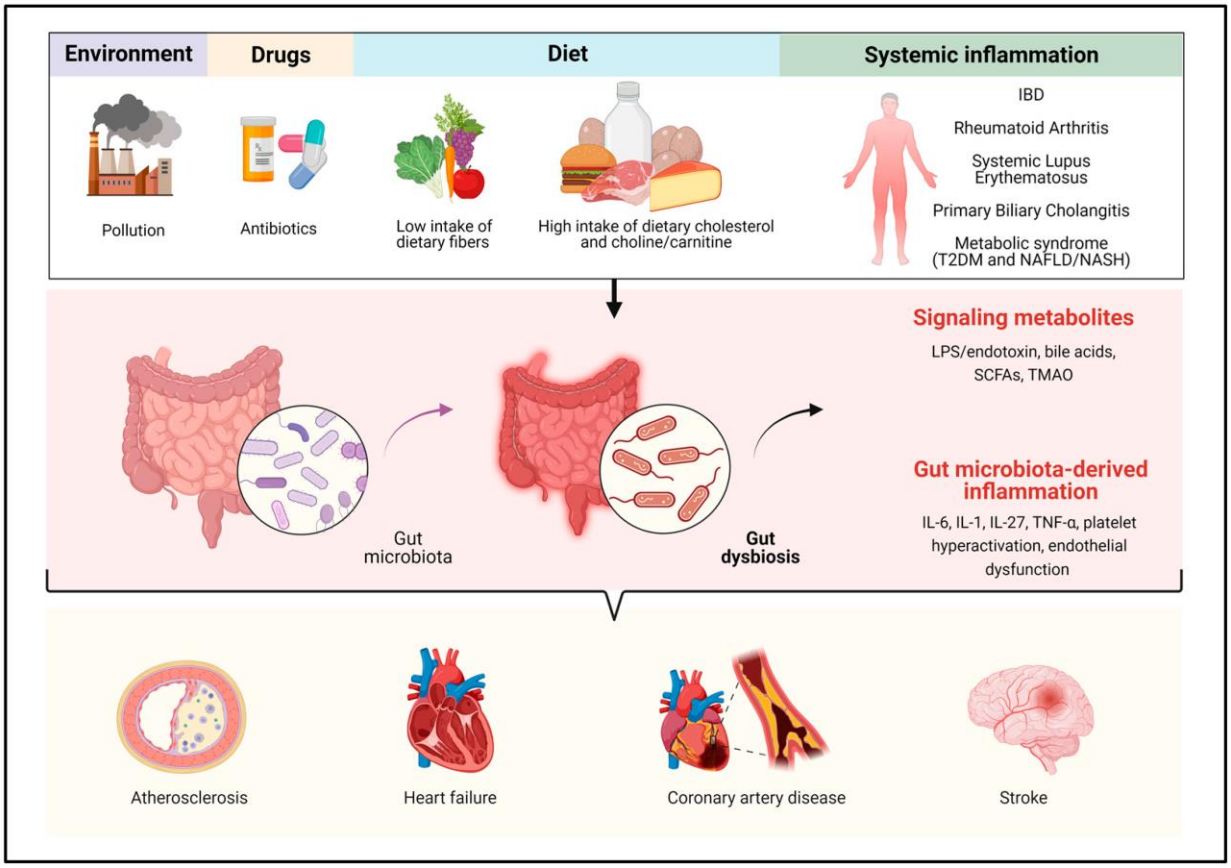
The effectiveness of therapy was assessed according to the criteria described above and consisted of:

a. excellent - in 24 (80%) patients;

b. good - in 5 (16.7%) patients;

c. satisfactory – in 1 (3.3%) patient.

Tolerability was good in 29 (96.7%) patients and poor in 1 (3.3%) patient. Complications of erosive and ulcerative lesions of the gastrointestinal mucosa, such as bleeding, were absent in all patients.



Conclusion

The main premise of this study was the information that the use of all PPIs except pantoprazole may increase the risk of recurrent myocardial infarction by 40% in patients receiving clopidogrel within the first 90 days after initial hospitalization. 4]. This was the basis for setting the study time. A number of clinical studies have shown that taking pantoprazole does not affect the efficacy of clopidogrel [11]. In addition, compared with other PPIs, pantoprazole has been shown to have a minimal potential for drug interactions, with no clinically significant interactions with other drugs reported in comparative studies [12, 13]. Pantoprazole can be used concomitantly with NSAIDs such as diclofenac, piroxicam, and naproxen without the risk of adverse effects on their metabolism [14]. When used concomitantly with diazepam, pantoprazole provided a higher level of safety than esomeprazole [15]. According to other reports, pantoprazole is the drug of choice among PPIs for the treatment of patients with gastroesophageal reflux disease in the presence of comorbidities and in elderly patients [12, 16, 17].

The treatment strategy for patients with cardiovascular disease requiring regular use of antiplatelet agents and/or anticoagulants, i.e., the appropriateness of prophylactic use of PPIs, is determined by the presence of risk factors for bleeding [10]. In the patients included in this study, an average of 3 risk factors were identified, which justifies the use of Controloc for prophylactic purposes. The results of the study showed that the healing rate of erosive and ulcerative lesions after oral administration of Controloc at a dose of 40 mg per day for 1 and 3 months was 82.1% and 96.4%, respectively. Excellent and good efficacy were noted in 96.7% of patients. No bleeding or adverse cardiovascular events (recurrent myocardial infarction, stroke, etc.) were observed during treatment with Controloc. The drug was well tolerated in almost all patients. An adverse effect in the form of dizziness was observed in 1 patient (3.3%) during the treatment period. This event was mild, did not require discontinuation of therapy, and resolved when Controloc was discontinued. Based on the data obtained during the study, the following conclusions can be drawn:

Controloc does not cause an undesirable increase in the anticoagulant effect of warfarin (i.e., these drugs can be used simultaneously).

In patients taking clopidogrel, concomitant use of Controloc does not reduce the effectiveness of clopidogrel.

The inclusion of Controloc in the complex treatment of patients with cardiovascular diseases who have 2 or more risk factors for bleeding and erosive and ulcerative changes in the mucous membrane (esophagus, stomach, duodenum) leads to the healing of erosive and ulcerative changes in the mucous membrane within 1-3 months and prevents complications of anticoagulant therapy (bleeding).

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