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THE APPLICATION EXPERIENCE OF SIMPONI (GOLIMUMAB) IN THE SECOND LINE OF BIOLOGICAL THERAPY (AFTER INFLIXIMAB) IN THE PATIENT WITH ULCERATIVE COLITIS

ABSTRACT

The article presents the clinical case analysis of the patient with diagnosis: ulcerative colitis of overall affection with clinical-laboratory results. The effect of baseline therapy with transition to genetically engineered biological therapy with the medicine "infliximab". The development of secondary resistance to the medicine "infliximab" and prescription of "golimumab" in the second line of biological therapy.

Keywords: ulcerative colitis, infliximab, golimumab.

INTRODUCTION

The relevance of inflammatory bowel disease (further IBD) in different regions of the world considerably varies. So, the frequency of ulcerative colitis (further UC) according to different researchers makes from 21 to 268 cases, and the Crown disease (further CD) from 9 to 199 cases per 100 thousand population, reaching the maximal indicators in the countries of Scandinavia, North America, Canada, Israel. The incidence increase of UC is 5-20 cases a year, CD - 5-15 cases a year per 100 thousand population.

According to epidemiological researches abundance of IBD in the European part of Russia makes 20,4 per 100 thousand population for UC and 3,7 per 100 thousand population for CD.

It is important to note that IBD develop mainly at the young age (mean age of the patients - 20-40 years).

The peculiarity of disease incidence in our country is a triple dominance of the severe complicated IBD forms with a high lethality due to late diagnostics. IBD within the first year of the disease is diagnosed only in 25% of cases,

in other cases the diagnosis was made 3-12 years since the beginning of clinical symptoms. The frequency of complications makes 55% for CD diagnosis during the period up to three years, for later diagnostics — in 100% of cases. Heavy complications develop in 29% of cases at late diagnostics of UC.

IBD is diagnosed on the basis of assessment of complaints, anamnesis, clinical picture of disease, data of a complex of endoscopic, radiological, histologic and laboratory tests.

For many years the treatment of IBD

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was limited by the use of the following medicines of baseline therapy: sulfasalazine aminosalicylates - it is and derivative of 5-aminosalicylic acid (5-ASA), glucocorticosteroids (GCS), immunosupressors of both chemical biological nature. However, approximately 35% of cases showed steroid-resistant or steroiddependent current of IBD and also resistance not only to hormones, but also to immunosupressive medicines is developed that leads to heavy complications, operative measures and disability of people of young workingage.

The introduction of biological medicines in the scheme of treatment of IBD allowed increasing considerably a share of the patients reaching stable remission in short terms.

MATERIALS AND RESEARCH **METHODS**

The patient MTV, 55 years old with the diagnosis: ulcerative colitis, overall affection of colon, at clinical remission stage.

Extraintestinal joint manifestations (polyarthritis). Nephropathy. Ambiopia OD. Incomplete complicated cataract. Astigmatism left.

From the anamnesis it is known that for the first time bloody stool with mucilage, pains and burning in anus and rectum developed after the delivery in 1981. She received conservative treatment concerning chronic anal fissure, without effect. In 1994 she was operated concerning chronic hemorrhoids, chronic back anal fissure, rectum polyp. After surgical treatment the patient noted health improvement. Since 1994 to 2000 she felt well. Since 1999 to 2000 - a personal stressful situation. In 2000 within 2 months she used tea to weight loss. The complaints of bloody stool 15 times a day appeared on the background of weight loss. The treatment of acute intestinal infection with short-term effect was carried out in central republican hospital.

In 2002 the patient's complaints were bloody stool with mucilage to 8 times a day, IBD was suspected. The patient was sent to clinical-consultation department of Republican hospital No.1 where ulcerative colitis was diagnosed (examination results were not saved). The treatment was sulfasalazine. Since 2002 to 2011 – periodic exacerbations of the disease: about 5 times a year in the form bloody stool with mucilage, abdominal pains, weakness. She began to receive the fissile treatment since 2011 - hormonal therapy, medicines 5-ASA, periodically was hospitalized. In April, 2012 the patient was given the 3rd group of disability.

Since August 16, 2012 the patient was administered genetic-engineering therapy: infliximab (Remicade) in 300 mg introduction dose (inductive course according to the instruction - 0-2-6 week, then maintenance therapy each 8 weeks), acceptability was satisfactory.

The patient felt improvement of health on the background of the therapy - formed stool was 2-3 times a day without pathological admixtures. Rectosigmocolonoscopy at 22.11.12 after the inductive course of biological therapy: examination was done to the hepatic angle. There were liquid stool masses in the colon. Mucous transverse colon was pink, vascular pattern was traced, haustration was kept. Mucous of the descending colon was hyperemic. Mucous of the sigmoid colon was hyperemic, moderately hydropic, irregular erosive, more expressed in distal departments, no folding. Rectum mucous was hydropic, hyperemic, covered with irregular sores, fibrin, tender in contact.

Clinical remission was recorded after a year therapy of infliximab. According to rectosigmocolonoscopy data at 1.08.13: ulcerative colitis of the left colon part, moderate activity (the device was carried into the caecum head. Bauhin's valve was of lip form. The moderate liquid feces complicating detailed examination were found in the lumen of the right part of intestine. The expressed vascular pattern was throughout colon mucous, moderately hyperemic. Mucous of sigmoid colon was hyperemic, moderately hydropic. centers of ulcers and erosion remain with fibrin imposing. Rectum mucous was hydropic, hyperemic). January, 2014 after 11 infusions of infliximab – bleedings in the mornings, during the day – bloody stool to 8 times a day. According to the emergency symptoms the patient was hospitalized to State Budgetary Institution of the Republic of Sakha (Yakutia) Republic hospital №2, coloproctology department where the exacerbation of ulcerative colitis was diagnosed. Antiinflammatory treatment was carried out (prednisolone, 5-ASA, azathioprine). The patient noted improvement of health (stool 3-4 times a day), dose increase of infliximab up to 10 mg/kg was recommended. The patient felt well after infliximab increased dose. Since May, 2014 the patient noted stool acceleration to 6 times a day, blood impurity, deterioration of endoscopic picture without histologic material was also noted. Medicine infliximab was cancelled due to its developed secondary inefficiency. Date of the last infusion was at 30.04.2014.

The experts concilium made the decision to change biological medicine - golimumab was chosen (Simponi) completely human monoclonal antibody. PURSUIT research data proved its effectiveness in bionaive patients with ulcerative colitis, and also golimumab safety for patients with rhematoid and psoriatic arthritis in the second, third or fourth line of biological therapy. Injections of inductive course of 200 mg dose subcutaneously were done at 11.07.2014 and 25.07.2014. No allergic reactions to medicine were recorded.

Then golimumab was injected 100 mg subcutaneously every month, patient's acceptability was good, without undesirable reactions. There were no complaints after inductive course, stool was 1-2 times a day, without blood and mucilage. Clinicalendoscopic remission was recorded after 4 injections.

In 1,5 years of therapy there weren't complaints, formed stool was 1-2 times a day without pathological impurity. According to rectosigmocolonoscopy data at 1.12.2015 - there were a moderate degree of activity: examination was done to the descending part of colon. Folds were routine, colon tone was normal. Mucous sigmoid and rectum were 30 cm from anus hyperemic, dim, vascular pattern was not traced with multiple subepithelial hemorrhages and surface ulcer defects were covered with fibrin, sizes from 0,2 to 0,5 cm. Multiple pseudopolyps were to 0,3 cm size in rectum.

After 19 injections of golimumab in December, 2015 the compelled break was made in biological treatment, in connection with the long-lived traumatology hospitalization of the patient (spine injury and 2,5 months of treatment). All this time clinical laboratory remission of the disease remained: stool was 1-2 times a day, without pathological impurity, blood tests without inflammatory changes.

According to the instruction of medical use of Simponi even after the miss of injection, a repeated induction was not provided therefore treatment was continued as the supporting course, the next injection was carried out on March 8, 2016, the patient felt well. Further injection was planned monthly subcutaneously in 100 mg dose.

Total 20 injections of golimumab with the considerable improvement of activity indexes of ulcerative colitis, good drug tolerance were carried out.

CONCLUSION

This clinical case shows the effectiveness of golimumab (Simponi) in the 2 line of biological therapy (after Infliximab) in patient with ulcerative colitis. The two-month break in therapy did not cause a clinical exacerbation of the disease.

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ACTUAL PROBLEMS OF THE URGENT ENDOSCOPIC TYPES OF EXAMINATION

ABSTRACT

Medical activity is impossible without organizational efforts, as well as without the information field, in organizational and tactical-strategic area, in the diagnostic phase of care. High-tech instrumental methods of examination are important in the diagnostic phase of emergency medical care. At this stage of empowerment and improving the safety of endoscopic methods of examination that contributes to effective use of existing equipment, reduce medical errors and improve the quality of the activities of health care.

In order to improve the quality of the diagnostic phase of emergency medical care, improve and enhance the safety of medical and surgical endoscopic technique we examined the possibility of urgent endoscopy in case of insufficient local training of the patient. Based on these results, algorithms and urgent fibrogastroscopy and fibrocolonoscopy we developed ways to improve the safety of medical and surgical intracavitary endoscopic procedures.

Keywords: urgency, safety, quality, endoscopy.

Topicality. Endoscopic methods of the examination of the upper and lower digestive tracts, upper and lower respiratory tracts are now widely used in medical practice. There are some

instrumental methods that are used in the first place for the diagnosis of acute surgical diseases - X-ray, ultrasound, endoscopy. It is possible to do therapeutic and operational

manipulations during diagnostic endoscopy that allows you to do EMF palliative or curative treatment during the diagnostic phase. Instrumental methods of examination (among other