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Treatment of Irritable Bowel Syndrome in Patients with Elevated Levels of Anxiety and/or Depression: Results of the Prospective Non-interventional Observational Program "KOMETA"

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Aim: to evaluate the efficacy and safety of Kolofort® in patients with irritable bowel syndrome accompanied by an anxiety-depressive disorder.
Materials and methods. A total of 70 patients with irritable bowel syndrome confirmed by Rome IV criteria and a HADS (Hospital Anxiety and Depression Scale) score of ≥ 8 points were included in an open, prospective, observational, non-interventional program. Patients received Kolofort® at a dose of 2 tablets twice daily for 8 weeks. The efficacy of the therapy was assessed according to the HADS, the Visual Analogue Scale for pain (VAS), and the Epworth Sleepiness Scale.
Results. After 8 weeks of therapy, the severity of anxiety and depression was significantly reduced ($p < 0.0001$): the mean score on the anxiety subscale decreased from 11.1 ± 2.4 to 5.3 ± 3.0, and from 7.6 ± 3.3 to 3.5 ± 2.8 on the depression subscale. The intensity of abdominal pain according to the VAS decreased from 4.8 ± 1.8 to 1.0 ± 1.0 ($p < 0.0001$). Clinically significant pain reduction (≥30 % from baseline) was recorded in 92.9 % of patients. The level of daytime sleepiness according to the Epworth scale decreased from 6.7 ± 4.2 to 4.0 ± 2.2 ($p < 0.0001$). Analysis of variance showed an association between reduced anxiety and decreased abdominal pain ($p = 0.0058$).
Conclusion. The results of the observational program demonstrate the efficacy and safety of Kolofort® in the treatment of irritable bowel syndrome accompanied by elevated anxiety and/or depression. The synergistic effect of the drug components provides improvement in both somatic and psycho-emotional symptoms of irritable bowel syndrome.
Keywords: irritable bowel syndrome, anxiety, depression, Kolofort®, psycho-emotional disorders
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Лечение синдрома раздраженного кишечника у пациентов с повышенным уровнем тревожности и (или) депрессии: результаты проспективной неинтервенционной наблюдательной программы «КОМЕТА»

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Цель: изучить эффективность и безопасность препарата «Колофорт®» у пациентов с синдромом раздраженного кишечника, сопровождающимся тревожно-депрессивным расстройством.
Материал и методы. В открытую проспективную наблюдательную неинтервенционную программу включены 70 пациентов с диагнозом «синдром раздраженного кишечника», подтвержденным Римскими критериями IV, и уровнем тревоги и (или) депрессии по шкале HADS ≥ 8 баллов. Пациенты получали препарат «Колофорт®»

в дозировке 2 таблетки 2 раза в сутки в течение 8 недель. Эффективность терапии оценивалась по шкале тревоги и депрессии HADS, визуально-аналоговой шкале боли (ВАШ) и шкале дневной сонливости Эпворта.
Результаты. Через 8 недель терапии отмечено достоверное снижение выраженности тревоги и депрессии ($p < 0,0001$): средний балл по подшкале тревоги снизился с 11,1 ± 2,4 до 5,3 ± 3,0, по подшкале депрессии — с 7,6 ± 3,3 до 3,5 ± 2,8. Интенсивность абдоминальной боли по ВАШ уменьшилась с 4,8 ± 1,8 до 1,0 ± 1,0 балла ($p < 0,0001$). Клинически значимое снижение боли (≥30 % от исходного уровня) зарегистрировано у 92,9 % пациентов. Уровень дневной сонливости по шкале Эпворта снизился с 6,7 ± 4,2 до 4,0 ± 2,2 балла ($p < 0,0001$). Дисперсионный анализ показал взаимосвязь между снижением тревожности и уменьшением абдоминальной боли ($p = 0,0058$).
Заключение. Результаты наблюдательной программы свидетельствуют об эффективности и безопасности препарата «Колофорт®» для лечения синдрома раздраженного кишечника, сопровождающегося повышенной тревогой и (или) депрессией. Синергетический эффект компонентов препарата обеспечивает улучшение как соматических, так и психоэмоциональных симптомов синдрома раздраженного кишечника.
Ключевые слова: синдром раздраженного кишечника, тревога, депрессия, Колофорт®, психоэмоциональные расстройства
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Introduction

Irritable bowel syndrome (IBS) is currently considered one of the most common disorders of the gut-brain axis, which are associated with altered gastrointestinal (GI) tract motility, visceral hypersensitivity, impaired mucosal function and immunity, microbiota imbalance, and specific interpretation of GI signals in the central nervous system. According to epidemiological studies, IBS is found in approximately 5 % of the population and is characterized by recurrent episodes of abdominal pain associated with defecation, and changes in the frequency and form of stool [1].

Psycho-emotional disorders are one of the components of the pathogenesis of IBS and largely determine the severity of somatic symptoms. In patients with various clinical forms of IBS, the prevalence of anxiety or depression is higher than in healthy individuals, reaching 40 and 38 % respectively in IBS with constipation [2].

Despite the high prevalence of anxiety-depressive disorders among patients with irritable bowel syndrome, they cannot be considered its primary cause. Their occurrence is a consequence of the chronic course of the disease and simultaneously a factor involved in maintaining and modulating the pathogenetic mechanisms of IBS, including visceral hypersensitivity and dysregulation of the gut-brain axis [3, 4]. Therefore, psychological correction methods play a significant role in the treatment strategy for patients with IBS today. Understanding the relationship between psycho-emotional disturbances and IBS provides a rational approach to the use of antidepressants [5].

In Russian clinical guidelines, the prescription of antidepressants to patients with IBS is aimed at reducing abdominal pain [6]. However, despite the proven clinical efficacy, the prescription of antidepressants has several limitations. Adverse effects are characterized by anticholinergic effects and an influence on neurotransmitter systems. The most commonly observed effects are dry mouth, urination retention, drowsiness, fatigue, orthostatic hypotension, weight gain, accommodation disorders, and, in some cases, QT interval prolongation.

Kolofort® is a biological medicinal product manufactured using a gradual release technology[1] and indicated for the treatment of IBS and functional dyspepsia. The active components of Kolofort® are technologically processed antibodies to tumor necrosis factor-alpha (TNF-α), S-100 protein, and histamine. Antibodies to S-100 protein exert anxiolytic, antiasthenic and nootropic effects. Antibodies to TNF-α exert a pronounced

[1] The State Pharmacopoeia of the Russian Federation. Ed. XIV. GPM.1.7.0001 "Biological medicinal products"; approved by Order of the Ministry of Health of the Russian Federation No. 377 dated July 07, 2023; effective from September 1, 2023. URL: https://pharmacopoeia.regmed.ru/pharmacopoeia/izdanie-15 / (accessed on May 25, 2026).

anti-inflammatory effect and contribute to the normalization of the balance between pro-inflammatory and anti-inflammatory cytokines. Antibodies to histamine exert spasmolytic, anti-inflammatory, and anti-edematous effects. The combination of the three active components provides a comprehensive effect on the peripheral and central pathogenetic mechanisms of IBS and functional dyspepsia[2].

The clinical efficacy and safety of Kolofort® were confirmed in a multicenter, double-blind, placebo-controlled clinical trial in patients with IBS. After 12 weeks of treatment, the intensity of abdominal pain according to the VAS decreased by ≥ 30 % in 90 % of patients, and the pain was completely relieved in 31 % of them. Kolofort® normalized the frequency and consistency of stool: according to the Bristol Stool Chart, improvement in patients with diarrhea-predominant IBS (IBS-D) was observed already after 2 weeks of therapy, and normal stool consistency was observed in 96 % of patients by the end of the course; in constipation-predominant IBS (IBS-C), stool frequency increased from 1–2 times per week to an average of 5 times per 7 days. The severity of abdominal pain, bloating, and flatulence was reduced, while nausea and a feeling of incomplete bowel emptying occurred less frequently [7].

The prescription of Kolofort® for the treatment of IBS helps not only to affect the pathogenesis of IBS, but also to influence the severity of psycho-emotional disturbances. The evaluation of the therapeutic potential and safety of Kolofort® in patients with IBS accompanied by elevated levels of anxiety and/or depression necessitated obtaining additional data in this population, which served as the basis for conducting the observational program "KOMETA".

Aim of the program: to study the efficacy and safety of Kolofort® in patients with IBS accompanied by anxiety-depressive disorder.

Materials and Methods

Study design and procedures

An open, prospective, observational, non-interventional program was approved by the Independent Interdisciplinary Ethics Committee (Protocol No. 04 dated February 14, 2025).

The observational program, conducted from February to December 2025, enrolled patients aged 18 to 45 years inclusive diagnosed with IBS according to Rome IV criteria. An additional inclusion criterion was an elevated level of anxiety and/or depression identified using the Hospital Anxiety and Depression Scale (HADS) (with a score of ≥ 8 on the anxiety and/or depression subscales). The severity of abdominal pain was assessed using the Visual Analogue Scale (VAS). Evaluation of daytime sleepiness, which reflects the functional state of the central nervous system and the level of emotional tension in patients, was performed using the Epworth Sleepiness Scale. Patients taking psychotropic drugs (neuroleptics, anxiolytics, antidepressants, hypnotics) were excluded from the study. All patients continued to receive therapy for their primary and concomitant conditions, including spasmolytics, laxatives, probiotics, pancreatin, and medications for cardiovascular diseases or hormonal disorders. Additionally, all patients received Kolofort® in accordance with the current Summary of Product Characteristics: 2 tablets twice daily for 8 weeks.

Further patient monitoring was conducted at weeks 4 and 8 of treatment and included the collection of complaints, physical examination, assessment of changes in abdominal pain according to the VAS, levels of anxiety and depression according to the HADS, levels of daytime sleepiness according to the Epworth scale, and the recording of adverse events and concomitant therapy. No additional patient monitoring was conducted after completion of the treatment course within the program.

To analyse the efficacy, the severity of anxiety and/or depression was assessed according to the HADS at weeks 4 and 8 of treatment with Kolofort®; the proportion of patients with a reduction in abdominal pain severity by ≥ 30 % from baseline at weeks 4 and 8 of treatment with Kolofort® was calculated; the relationship between the severity of the abdominal pain syndrome (according to the VAS) and the levels of anxiety and depression (according to the HADS) was evaluated. The safety of the treatment was assessed based on data on adverse events (number, relationship to Kolofort® intake, severity, seriousness, outcome). Changes in the level of daytime sleepiness were assessed using the Epworth scale at weeks 4 and 8 of treatment with Kolofort®.

Statistical analysis

Statistical data processing included descriptive statistical methods, parametric analysis methods (analysis of variance, mixed models analysis), and

[2] General characteristics of the medicinal product Kolofort®: authorization number LP-No. (000027)-(RG_RU). URL: https://www.lsgeotar.ru/drugs/kolofort-AGsq (accessed on May 25, 2026).

categorical data analysis (Fisher's exact test). Data are presented as means and standard deviations for continuous data, and as absolute and relative frequencies for categorical data. All calculations were performed using appropriate procedures of the statistical software (SAS).

Results

The study enrolled 70 outpatients. The mean age of the participants was 33.7 ± 7.9 years. Women predominated in the sample (n = 52; 74.3 %). Concomitant therapy was used in 54 out of 70 patients (77.1 %):

- medications for the treatment of diseases associated with acid secretion disorders (pantoprazole, rabeprazole, esomeprazole);
- medications for the treatment of functional gastrointestinal disorders (alverine citrate + simethicone, hyoscine butylbromide, mebeverine hydrochloride, trimebutine maleate);
- medications for the treatment of liver and biliary tract disorders (dry aqueous extract of artichoke leaves, ursodeoxycholic acid);
- laxatives (lactulose, macrogol 4000, sodium lauryl sulfoacetate + sorbitol + citrate, sodium picosulfate monohydrate, psyllium husk powder);
- medications promoting digestion (pancreatin).

Patients were allowed to use antidiarrheal drugs (loperamide, dioctahedral smectite).

All patients completed the full 8-week treatment course with Kolofort® without early withdrawal, which indicates high adherence and good tolerability of the therapy.

Dynamics of anxiety and depression parameters according to the HADS

At baseline, the mean score on the anxiety subscale was 11.1 ± 2.4, which corresponds to a clinically expressed level of anxiety. By week 4 of treatment, a statistically significant decrease in this parameter to 7.6 ± 2.9 was observed, and by the end of the course — to 5.3 ± 3.0 ($p < 0.0001$). The proportion of patients with anxiety scores < 8 was 35.7 % at week 4 and 72.9 % by week 8 of therapy. A similar trend was observed on the depression subscale: initially, the mean score was 7.6 ± 3.3, which is characteristic of subclinical depression in most patients. After 4 weeks of treatment, the score decreased to 5.4 ± 2.8, and by the end of the observation period — to 3.5 ± 2.8 ($p < 0.0001$). At the same time, the proportion of patients without signs of depression (HADS-D < 8) increased from 37.1 to 84.3 % at weeks 4 and 8, respectively. The dynamics of anxiety and depression levels according to the HADS, pain according to the VAS, and daytime sleepiness according to the Epworth scale are presented in the Figure.

Changes in abdominal pain severity according to the VAS

At baseline, the mean VAS score was 4.8 ± 1.8. By week 4 of therapy, the intensity of pain decreased by more than 1.5 times — to 2.7 ± 1.7, and by week 8 — to 1.0 ± 1.0 ($p < 0.0001$). After 4 weeks, a clinically significant reduction in pain intensity (by ≥ 30 % from baseline) was observed in 75.7 % of patients, and by the end of the course — in 92.9 % (Fig.). At the same time, the intensity of pain in most patients decreased to minimal values or disappeared completely.

Dynamics of daytime sleepiness according to the Epworth Sleepiness Scale

The mean Epworth Sleepiness Scale score decreased from 6.7 ± 4.2 to 4.0 ± 2.2 ($p < 0.0001$), indicating the absence of excessive daytime sleepiness in patients during treatment (Fig.).

Analysis of the relationship between pain, anxiety, and depression

Mixed models analysis showed a statistically significant relationship between anxiety symptom dynamics and a reduction in abdominal pain severity ($F = 2.7$; $p = 0.0058$), as well as a trend toward statistical significance for the association between decreased depression and abdominal pain scores ($p = 0.0557$).

Safety profile

During the observation period, four adverse events were recorded, indicating their low incidence. All adverse events were considered mild. No serious adverse events were recorded. The causal relationship to the investigational medicinal product was assessed as conditional in 1 case, unclassifiable in 1 case, and absent ("not related") in 2 cases. Clinical manifestations of the adverse events were characterized by increased irritability, headache, and excitability. In most cases, the adverse events were transient, did not require discontinuation of therapy, and resulted in recovery or spontaneous resolution. In one case, symptomatic therapy was prescribed (a single dose of an analgesic).

Discussion

The mean age of the patients enrolled was 33.7 ± 7.9 years, which corresponds to the period of professional and social activity in which IBS exerts its most pronounced effect on the quality of life and work capacity.

The results of the conducted observational program demonstrate the therapeutic effect of Kolofort® in patients with IBS combined with an anxiety-depressive disorder. After 4 weeks of treatment, a reduction in the severity of disease symptoms — abdominal pain, anxiety, and

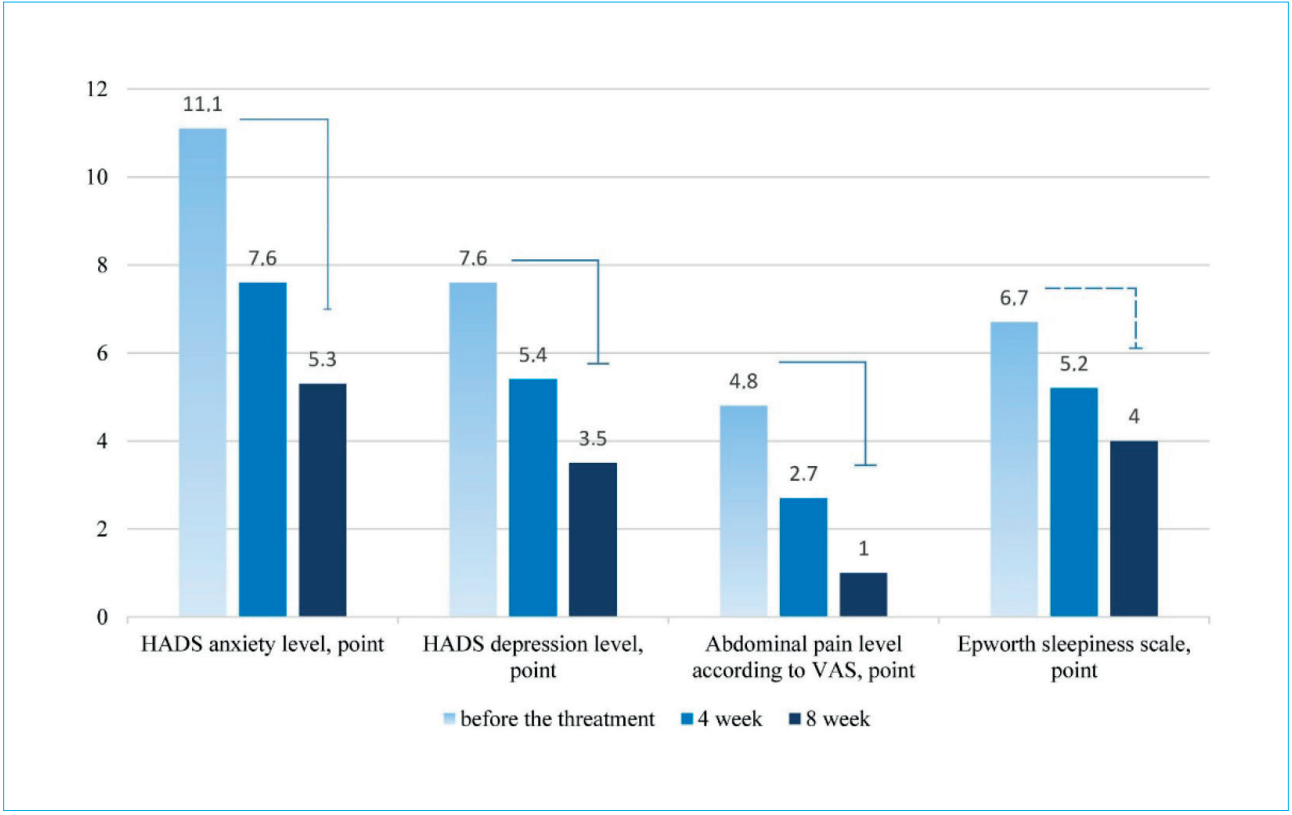

Figure. Dynamics of anxiety and depression levels according to the HADS, pain according to the Visual Analogue Scale, and daytime sleepiness according to the Epworth Sleepiness Scale

depression — was observed. By the end of the 8-week course, a stable clinical effect was achieved.

Emotional and mood dysregulation in patients with IBS serves as an important pathogenetic link in the development of the disease. Kolofort® exerts a modulating effect on the levels of anxiety and depression in patients with IBS, increasing the proportion of patients without signs of an anxiety-depressive disorder by more than two-fold by the end of the course. The consequence of the reduction in anxiety and/or depression levels was a decrease in abdominal pain severity according to the VAS, which is a key symptom of IBS. Additional analysis showed that the reduction of pain intensity was significantly associated with a decrease in anxiety levels in the patients.

A statistically significant improvement in sleep quality and reduced daytime sleepiness can be considered a consequence of reduced anxiety and the normalization of psychophysiological reactions in the body. At the same time, the absence of excessive daytime sleepiness is an additional advantage of Kolofort® therapy, distinguishing it from typical antidepressants used in clinical practice. This is important considering that the majority of patients with IBS represent an active, working-age population.

The low incidence of reported adverse effects during the observation period indicates high adherence and good tolerability of Kolofort® in outpatient practice. These results have important clinical significance, since safety is a key criterion when selecting the therapy for patients with chronic functional gastrointestinal disorders. Considering that IBS requires long-term treatment, the good tolerability of Kolofort® serves as an argument in favour of its prescription.

The obtained data confirm the key role of the gut-brain axis and the determining role of psycho-emotional factors in modulating visceral hypersensitivity. A reduction in anxiety and emotional tension is accompanied by a decrease in pain perception, highlighting the appropriateness of using medicinal products that affect both peripheral and central regulatory mechanisms.

Comparing the obtained data with the results of previous clinical trials and observational studies confirms the efficacy of Kolofort® in functional gastrointestinal disorders [6–8]. These studies noted that the drug exerts a comprehensive effect — anti-inflammatory, spasmolytic, and anxiolytic — due to the combination of technologically processed antibodies to tumor necrosis factor-alpha (TNF-α), S-100 protein, and histamine.

Thus, Kolofort® not only reduces the severity of abdominal pain but also eliminates signs of anxiety and depression. The positive dynamics of psycho-emotional and somatic symptoms confirm the pathogenetic rationale for using the drug in IBS, especially in patients with an anxiety-depressive disorder.

Study limitations

This study has several limitations. The observational design of the program, the lack of randomization, and the absence of a control group prevent establishing a causal relationship and make the results vulnerable to the influence of confounding factors. The presence of baseline IBS therapy, including antidiarrheal and spasmolytic drugs, may have influenced the disease outcomes; however, considering that the main objective of the study was to evaluate the effect of Kolofort® on anxiety and depressive states in patients with IBS, these limitations did not prevent an objective analysis of the obtained data.

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