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# Alternative Phytotherapy for Dyspeptic Symptoms After Eradication Therapy Using the Ventrap® Biologically Active Food Supplement

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**Abstract** The article discusses the results of using the biologically active supplement VENTRAP® , consisting of dried mulberry, black root, and large plantain, in addition to eradication therapy (ET) in 40 hospitalized patients suffering from Helicobacter pylori-associated chronic gastritis. Despite the implementation of highly effective eradication therapy (ET), 15-25% of patients continue to experience persistent dyspeptic symptoms (DS) such as a burning sensation and pain in the epigastric region, heaviness after meals, and early satiety, significantly worsening the patients' quality of life. VENTRAP has demonstrated high effectiveness and safety in eliminating (DS) and has been recommended as an alternative phytotherapy for the treatment and prevention of (DS) in patients with Helicobacter pylori-associated chronic gastritis.

**Keywords** Phytotherapy, Alternative medicine, Helicobacter pylori, Chronic gastritis, Gastroenterology, Dietary supplements, Dandelion, Elecampane, Great plantain

## 1. Introduction

Among stomach diseases, gastritis, functional dyspepsia, peptic ulcer disease, and stomach cancer are most frequently discussed. The history of studying stomach diseases dates back centuries in the development of medicine and healthcare; however, to this day, problems related to the pathologies of the upper gastrointestinal tract remain relevant. The complexity of solving this problem for medicine and healthcare is determined by the widespread prevalence of these diseases, the multifactorial nature of their causes, the polymorphism of symptoms, and the difficulty of diagnosis and statistical accounting [1,2,3].

Helicobacter pylori (H. pylori) is one of the most common bacterial infections worldwide, affecting nearly half of the global population. In fact, it is often stated that every second person on Earth is a carrier of H. pylori. This high prevalence makes it a significant public health concern, particularly due to its association with gastrointestinal diseases such as gastritis, peptic ulcers, and even gastric cancer. In African countries, approximately 80% of the population is infected, in South America about 70%, in Asia about 55%, and in Europe 47%. [3,4] In Central Asian countries, the prevalence of H. pylori exceeds 70%. In Uzbekistan, according to M.M. Karimov et al. (2018), the prevalence of H. pylori reaches 80-84%, with a mixed type of IceA1/IceA2 infection with the CagA genotype. In patients with chronic atrophic gastritis (B-type), the most frequently detected strain is Cag+ VacA s1 VacA m2 and IceA [5]. Cag+ VacA and VacA m2 and IceA [5] strains were most frequently detected in patients with chronic hepatitis C (B-type).

It should be noted that H. pylori infection is mainly acquired in childhood and persists throughout life without special treatment, which ensures its transmission route - domestic, fecal-oral - through water and food products, kissing, etc. [6,7,8]. One of the risk factors for the development of chronic gastritis is advanced age, especially over 60 years old [9]. Both older and contemporary authors studying the development and prevalence of gastritis, functional dyspepsia (FD), and gastric cancer pay considerable attention to the dietary risk factor. According to the Chinese author Yuan Li (2020), a survey of patients with gastritis showed that the majority of them (58.2%) attribute their illness to dietary and behavioral factors. According to the author, the factors of dyspeptic disorders in all men were irregular meal portion sizes, barbecue, snacks, and alcohol, while sweets were the only dietary factor associated with all symptoms in women [10,11].

20-30% of the population constantly or periodically experiences dyspeptic symptoms. However, research has shown that a smaller portion (35-40%) belongs to the group of diseases classified as organic dyspepsia, while a larger portion (60-65%) is attributed to functional dyspepsia (FD). The etiology and pathogenesis of FD syndrome remain insufficiently studied. The role of H. pylori infection in

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causing functional dyspepsia (FD) is still debated among experts. Some believe it plays a part, while others argue that it's not a significant factor. Current data does not provide grounds for considering H. pylori as a significant etiological factor in the development of dyspeptic disorders in most patients with functional dyspepsia. Eradication may only be beneficial for 5% of such patients. Treatment of H. pylori-associated gastritis is a complex and lengthy process, requiring significant economic, labor, and time costs not only from medical staff but also from the patient and their family. Ideally, etiotropic therapy (ET) should lead to 90% eradication of H. pylori, which is achieved by the simultaneous use of 2-3 antibiotics. However, doctors in many countries are observing a decrease in the effectiveness of ET to an unacceptable level of ≤ 80%. The main reasons for unsuccessful eradication are the emergence of antibiotic -resistant H. pylori strains [12,13].

**Research Objective:** To study the clinical efficacy and tolerability of the dietary supplement VENTRAP® manufactured by "OMAR CARE" (Uzbekistan).

## 2. Materials and Methods

The study included 40 patients aged 19 to 60, with an average age of 35+16.5 years, with a verified diagnosis of HP associated with CG. The diagnosis was established based on EFGDS and targeted biopsy followed by a rapid urease test on the NR. Chronic gastritis, verified in the patient, and the clinical symptom complex characteristic of FD, were combined when making a general diagnosis and encrypted in the ICB-10 using both the "chronic gastritis" (K 29) and "fever functional disorders" (K 31). All patients completed a special questionnaire designed to assess the likelihood of acid-related diseases, including functional dyspepsia (FD). According to the questionnaire, epigastric pain syndrome was noted in cases where the patient reported moderate or severe pain or a burning sensation in the upper abdominal area at least once a week. At the same time, the pains were not permanent, they were related to eating or arose at night, did not localize in other parts of the abdomen, did not decrease after defecation and did not accompany signs of dysfunction of the gallbladder or Oddy's sphincter. Epigastric pain syndrome is often accompanied by postprandial distress syndrome.

Postprandial distress syndrome was noted when patients experienced a sense of heaviness in the upper abdomen or felt full too quickly after eating, at least several times a week. Additionally, postprandial distress syndrome was sometimes associated with nausea and epigastric pain. Symptoms were assessed using a three-point system, where:

0 - absence of symptoms;
1 - poorly expressed, periodic symptoms - rarely;
2 - moderately expressed symptoms - quite often;
3 - pronounced, permanent symptoms - constant.

Patients were divided into 2 groups, comparable in terms of gender, age, and clinical course of CG and FD. The first control group of patients received standard eradication therapy consisting of a proton pump inhibitor (PPI), amoxicillin at a dose of 1.0 g 2 times a day, clarithromycin at a dose of 500 mg 2 times a day, and tricalcium bismuth citrate at a dose of 120 mg 4 times a day for 10 days. Another group of patients (the main group) on the background of similar eradication therapy for 4 weeks also received the dietary supplement VENTRAP® 370 mg 1 tablet 3 times a day. Control tests for NR infection were conducted 4 weeks after the completion of eradication therapy using the C14 respiratory urea test. The anti-secretory efficacy of the drugs was assessed by topographic pH-metry using glass-surface probes and their registration on the "AGM-03" microprocessor acidogastrometer.

## 3. Results and Discussion

The study included patients with chronic hepatitis who were hospitalized, both sexes, aged 18 and older, who agreed to participate in the study. Exclusion criteria for the study were pregnancy, lactation, calculous cholecystitis and/or mechanical obstruction of the biliary tract, increased sensitivity to the components of the drug, the patient's participation in other clinical trials in the last 30 days, and intestinal obstruction.

The studied plant pest VENTRAP® consists of the following medicinal herbs: *Plantago major (*40%), *Taraxacum officinale* (30%), *Inula helenium* (30%). *Plantago major* (Large and ordinary traveller). *Folium plantaginis majoris* (Latin) and *herba plantaginis majoris* (Herba Plantaginis majoris recens) are used as medicinal raw materials. Taraxacum officinale (medicinal common bile duct) exhibits biliary, fever-reducing, laxative, relieving, calming, spasmolytic, and mild sleep-inducing effects. Inula helenium is used as an exfoliating agent and in the treatment of gastrointestinal diseases.

The clinical presentation of chronic gastritis (CG) and peptic disorders (PD) in patients was characterized by ulcerative syndrome in 24.3% of cases and postprandial distress syndrome in 20.6%. A mixed form of the disease occurred in 45.3% of patients. Pain in the upper abdomen was reported in only 36.5% of cases, with 62% of those patients experiencing pain after eating. Nighttime pain affected 82% of patients, and in 89% of these cases, the pain was severe enough to disrupt sleep.

Additional symptoms included early satiation, noted by 85.7% of patients, burning sensations mainly in the epigastric region (85.4%), and nausea, which was reported in 92.5% of cases.

The most significant causes of functional dyspepsia (FD) in these patients were:

- Acid-related factors
- Genetic predisposition
- A history of non-responders (NR)
- Smoking and alcohol use
- Frequent toxic infections
- Dietary factors such as excessive spicy or salty food,

late-night meals, and overeating
- Psychosocial factors

Nutritional recommendations for all FD patients included frequent (5-6 times a day), small, and fractional meals, with restrictions on fatty and spicy foods, as well as coffee. It was recommended to refrain from smoking, alcohol consumption, and NSAIDs.

Studies to evaluate the effectiveness of the eradication treatment regimen were conducted 8 weeks after the start of treatment. According to the protocols of the VI Maastricht Consensus, 85% of the eradication rate is "satisfactory." Thus, according to our research, the eradication rate indicators of the main group of patients who received vonprazole meet the criteria of "satisfactory."

Table 1 presents the dynamics of clinical manifestations of the disease before and after the course of treatment.

The observation results showed that, in the control group of patients, there was a significant reduction in the severity of epigastric pain syndrome by 58.5% and a decrease in the sensation of burning in the epigastric region by 48.8%. This improvement was attributed to the use of proton pump inhibitors (PPIs), which helped alleviate pain symptoms. However, the severity of postprandial distress syndrome in the control group did not show statistically significant changes. However, in the control group of patients, the severity of postprandial distress syndrome practically did not undergo statistically significant changes. The severity of both epigastric pain syndrome and epigastric burning decreased by 84%. Additionally, there was a marked reduction in postprandial distress syndrome, with the feeling of heaviness after meals decreasing by 60% and early satiation by 71.5%.

**Table 1.** Dynamics of Clinical Parameters Before and After Treatment

| Parameter | Main Group (ET + VENTRAP) Before Treatment | Main Group (ET + VENTRAP) After Treatment | Control Group (ET) Before Treatment | Control Group (ET) After Treatment |
|---|---|---|---|---|
| Epigastric pain | 2.8 ± 0.2 | 0.45 ± 0.05* | 2.7 ± 0.14 | 1.12 ± 0.3* |
| Burning sensation in epigastric region | 2.6 ± 0.3 | 0.41 ± 0.03* | 2.7 ± 0.2 | 1.6 ± 0.08* |
| Feeling of heaviness after eating | 3.0 ± 0.3 | 1.2 ± 0.07* | 2.8 ± 0.5 | 2.5 ± 0.4 |
| Early satiety | 2.8 ± 0.2 | 0.8 ± 0.05* | 2.7 ± 0.3 | 2.5 ± 0.05 |

*Note: the difference is significant between the indicators of the compared groups ($p < 0.05$)*

**Table 2.** Comparative Dynamics of pH Indicators in Control Points in Patients with CG and FD

| Measurement Location | Main Group (n=20) Before Treatment | Main Group (n=20) After Treatment | Control Group (n=20) Before Treatment | Control Group (n=20) After Treatment |
|---|---|---|---|---|
| “Lake” | 1.1 ± 0.05 | 4.5 ± 0.06* | 1.05 ± 0.05* | 4.6 ± 0.07* |
| Fundus of the stomach | 1.0 ± 0.06 | 4.2 ± 0.08* | 0.9 ± 0.04* | 4.3 ± 0.08* |
| Body of the stomach (posterior wall) | 0.9 ± 0.05 | 4.4 ± 0.07* | 1.0 ± 0.08* | 4.2 ± 0.07* |
| Body of the stomach (anterior wall) | 0.8 ± 0.06 | 4.6 ± 0.07* | 0.7 ± 0.07* | 4.2 ± 0.08* |
| Antrum (lesser curvature) | 1.6 ± 0.08* | 6.6 ± 0.06* | 1.5 ± 0.07* | 5.9 ± 0.05* |
| Antrum (greater curvature) | 1.3 ± 0.07* | 6.7 ± 0.07* | 1.2 ± 0.06* | 6.5 ± 0.07* |
| Duodenal bulb (anterior wall) | 4.2 ± 0.6* | 6.9 ± 0.4* | 4.1 ± 0.4* | 6.7 ± 0.4* |

*Note: the difference is significant compared to the indicators before and after treatment ($p<0.05$)*

**Table 3.** Dynamics of Certain Blood Test Parameters Before and After Treatment

| Indicator | Main Group Before Treatment | Main Group After Treatment | Control Group Before Treatment | Control Group After Treatment |
|---|---|---|---|---|
| Hemoglobin (g/L) | 140.5 ± 28.6 | 133.35 ± 40.1 | 128.2 ± 28.8 | 126.4 ± 29.5 |
| Erythrocytes (10^12/L) | 4.4 ± 0.09 | 4.2 ± 0.1 | 4.2 ± 0.07 | 4.1 ± 0.08 |
| Leukocytes (10^9/L) | 6.0 ± 0.32 | 6.1 ± 0.41 | 5.3 ± 0.26 | 5.5 ± 0.3 |
| ESR (mm/h) | 4.0 ± 0.59 | 7.8 ± 2.21 | 8.0 ± 0.89 | 8.6 ± 1.19 |

Topographic, transendoscopic pH measurements of patients with CG and PD revealed gastric juice hypercysticity (Table 2), which was expressed in a decrease in pH in the area of active acid formation (the anterior and posterior walls of the stomach and the "ball" below 2.0). In the area of acid neutralization in the antral part of the stomach, pH values were also significantly reduced compared to similar indicators in healthy individuals. This indicates that in NR associated with gastric diseases, sub-and decompensated disruptions in the process of hydrochloric acid neutralization in gastric juice are observed. In this case, the alkalizing function of the antral region was considered to be preserved at pH > 5 in the middle third of the antral region.

Control studies of gastric juice pH parameters in dynamics were conducted 6 weeks after the start of treatment during repeated esophagogastroduodenoscopy procedures (Table...). During these periods, significant shifts in the mean pH values of gastric juice were achieved in both observation groups. This was expressed, first and foremost, in an increase in the pH indicator in the zone of active acid formation ("ball," stomach arch, anterior and posterior walls of the stomach) to optimal values (on average 4, 0). the pH of the active acid neutralization zone after the course of treatment showed some significant differences. In this zone (the greater and lesser curvature of the antral part, the anterior wall of the DPK bulb), the pH value above 5.0 is considered optimal. The acid neutralization activity is also determined by the difference between the average indicators of the active acid formation zone and the acid neutralization zone. In the control group of patients, the pH of the gastric juice in the small curvature of the antral region was less than 5.0 and amounted to 4.5.

A study of the overall blood count of patients who received VENTRAP® showed that no adverse effects of the phytopreparation on the studied blood plasma parameters were observed (Table 3).

The evaluation of the effectiveness of the VENTRAP® dietary supplement showed that the treatment results were rated as "good" in 100% of patients.

Adverse reactions: no side effects or negative symptoms were observed during the treatment period. The herbal preparation was well tolerated by patients. Some patients noted a bitter taste of the supplement, but this did not require discontinuation.

Many clinical and epidemiological studies have established that chronic gastritis is often detected in patients with functional dyspepsia (FD) syndrome. However, no correlation was found between the severity of "gastritis" changes and the presence of dyspeptic disorders in patients. Accordingly, the absence of any connection between gastritis changes in the gastric mucosa and the presence of dyspeptic complaints in patients has been proven. The presence of HP-associated gastritis does not explain the occurrence of dyspepsia symptoms.

None of the three current classifications of chronic gastritis ("Sydney," 1990; "Houston," 1994; OLGA classification, 2008) contains a section on the assessment of clinical manifestations. The diagnosis of chronic gastritis (CG) provides information about morphological processes in the gastric mucosa from the perspective of their significance as precancerous conditions. CG detected during endoscopic examination and the clinical symptom complex characteristic of functional dyspepsia can and should be combined when making a general diagnosis. Diagnosing FD allows for optimizing patient treatment by determining the choice of certain groups of medications.

It should be noted that despite the seeming abundance of herbal remedies, modern domestic gastroenterology still experiences a "medicinal shortage" as it adheres to the proven and true, one might say canonized, principle of "treating not the disease, but the patient." In modern clinical practice, the variants of gastrointestinal tract pathology are so diverse that the available remedies do not always meet patients' needs. All of the above proves the necessity of creating a domestic highly effective herbal remedy that combines the properties of both gastroprotector and prokinetic.

The studies conducted showed that in both observed groups of patients, eradication rates were 85%, which is assessed as a satisfactory result according to the Maastricht consensus. However, conducting eradication therapy, despite good eradication results, did not contribute to the alleviation of disease symptoms. In a certain number of patients with CG and concomitant FD, partial alleviation of FD symptoms was observed, but this was primarily noted in patients with epigastric pain syndrome FD. This was due to the fact that patients were taking proton pump inhibitors (PPIs), which contributed to the alleviation of pain symptoms. However, in the control group of patients, we practically did not observe alleviation of disease symptoms in relation to the group of patients with postprandial symptoms, as well as in individuals with mixed forms of FD. Unlike the control group, the experimental group of patients who received VENTRAP® alongside eradication therapy showed a significant positive trend in alleviating painful, postprandial, and mixed forms of FD. This was due to the fact that VENTRAP® dietary supplement has a comprehensive positive effect on both gastroprotective and motor functions of the stomach. The herbal dietary supplement VENTRAP® was well tolerated by patients, without any side effects that would require discontinuation.

Thus, VENTRAP® dietary supplement can be recommended for use in the treatment of patients with chronic gastritis and FD in combination with eradication therapy.

# 4. Conclusions

After these experiments, we have come to certain conclusions regarding the use of the dietary supplement VENTRAP® in conjunction with eradication therapy for patients with H. pylori-associated chronic gastritis (CG) and functional dyspepsia (FD). The findings are as follows:

1. The use of the dietary supplement VENTRAP®, which contains *Plantago major*, *Taraxacum officinale*,

and *Inula helenium*, in combination with eradication therapy in patients with *H. pylori*-associated CG and FD, significantly contributes to the alleviation of clinical symptoms of these conditions.

2. The clinical benefits of VENTRAP® are demonstrated by the reduction in both abdominal pain and postprandial distress syndrome symptoms in patients with FD.
3. VENTRAP® was well tolerated by all patients when used alongside standard treatments for CG and FD, with no reported side effects observed during the study.

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