

**Evaluation of the efficiency of enterosorbent White Coal[®]
in patients with the diseases of hepatobiliary system**

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From the earliest times, there have been two different approaches to medical treatment. The first one is to administer drugs into the system (pharmacological therapies) and the other one is to purge the system of the foreign matter entering from without or formed within the body. The latter includes the method of enterosorption, a therapeutic technique applicable in a wide range of health conditions and problems. Enterosorption is based on the capacity of enteric sorbents to bind and eliminate xenobiotics, potential allergens, microbial agents and their respective toxins and intermediate/terminal metabolic products that penetrate into the gastrointestinal tract and remain therein in various disease [30]. Enteric sorbents are medical products with a high absorption capacity, resistant to destruction in the gastrointestinal tract (GIT) and binding exogenous and endogenous substances in the chyme, secreted into the lumen of GIT through the walls via adsorption/absorption, ion exchange and complex formation [30]. Currently, there is much interest in the research community and among medical professionals in clinical applications of silica dioxide (SiO₂)-based enteric sorbents, since these products possess a number of positive pharmacological properties compared to the other groups of sorbents. Such positive pharmacological properties include the large sorption capacity for microbial agents and bacterial toxins, the option to take moderate therapeutic doses of enteric sorbents due to their larger active surface and the high rate of binding with bacteria and toxins, which exerts the rapid therapeutic effect [10]. The enteric sorbents based on the super-finely dispersed silica dioxide do not cause constipations; they are characterised by lack of toxicity, hypoallergic properties and selective action; as a result, enterosorption occurs with minimal loss of important micronutrients [10].

One of the most promising products in this category is the White Coal® enteric sorbent with a number of positive pharmacological effects, which allows for a wide range of applications in various health conditions. An important mechanism of action of the White Coal® sorbent is binding of various toxic substances, as well as selective sorption of bile pigments (bilirubin/cholesterol derivatives), free and conjugated bile acids. This allows for a substantial reduction of the toxic burden affecting the excretory organs, primarily the liver, which serves as a rationale of using enteric sorbents as a part of multimodality therapy for hepatobiliary disease [12].

In this study of detoxification properties we have explored the influence of White Coal® enteric sorbent on clinical laboratory findings in patients with drug-induced liver toxicities. Due to a current prevalence of chronic conditions of internal organs and concomitant chronic infections, antibacterial drugs and schedules are typically used, which substantially increases complication rates, including hepatic disorders, such as toxic hepatitis (TG). Therefore, it is expedient to develop rational approach to management of liver toxicities using the products metabolised outside hepatic parenchyma and therefore free of adverse hepatic effects. The authors of this paper have assessed 88 patients with chronic drug-induced TG, age 25 — 50 years, randomised into 2 groups, the main group (35 subjects) and the control group (33 subjects). All patients assessed received conventional basic therapy; the patients in the main group additionally received the White Coal® enteric sorbent at 3-4 tablets orally 3-4 times a day for 15-20 days. It was found that in addition to improved liver function and facilitation of full and stable clinical and biochemical remission, inclusion of White Coal® into the therapeutic protocol for drug-induced TG produced recovery of laboratory findings impaired in endogenous toxicity, namely the levels of medium-weight molecules and circulating immune complexes [29].

Enterosorption with the White Coal® enteric sorbent was also found to be effective in alcohol-induced liver damage. The authors of this study have observed that adding White Coal® to the therapeutic protocols in alcoholic hepatopathy is very efficient in a pathogenetic sense, since this facilitates an apparent relief of

endogenous toxemia along with reduced oxidative stress. Most patients report improved health within 4-6 days after initiation of the suggested therapy [9].

Previous research has demonstrated that using the White Coal® enteric sorbent in the treatment of patients with liver disease of toxic origin, combined with chronic non-calculous cholecystitis and obesity allowed increasing clinical and biochemical efficacy of treatment, as well as restoring the balance of the main pro-inflammatory and anti-inflammatory cytokines, such as IL-1 β , TNF α , IL-4 and IL-6 and the levels of medium-weight molecules, which play an important pathogenetic role both in hepatobiliary disease and obesity [4, 28, 29].

The favourable effect of the White Coal® enteric sorbent on clinical and laboratory findings has also been noted in multimodality therapy of patients with liver cirrhosis (LC). According to current pathophysiological research, among the factors that trigger LC and the closely related hepatic fibrosis, an important role is played by excessive activation of lipid peroxidation in the setting of suppressed activity of enzymes responsible for antioxidant protection with subsequent development of endogenous metabolic toxicity syndrome (EMTS). The standard therapy for LC (especially that of viral origin) lacks efficacy at times and leads to adverse effects. Enterosorption is currently by far one of the most promising methods of detoxification therapy. The patients with LC were randomised and assessed in 2 groups: the main group (36 patients) and the control group (32 patients). The aetiology of hepatic damage was viral in 29 patients (42.6%) and alcoholic in 26 patients (38.3%); in 13 subjects (19.1%) LC was of a mixed alcoholic and viral aetiology. According to enzyme immunoassay (EIA) findings, HCV contributed to 36 cases of LC (85.7%), whereas HBV contributed to 6 cases of LC (14.3%). The severity of LC corresponded to modified Child-Turcotte-Pugh Class A or Class B in all patients. The duration of LC was 2 to 6 years (mean 3.1 ± 1.2 years). The patients in both groups were managed according to the general requirements of current therapy guidelines. In addition to that the patients in the main group received White Coal® at the dose of 3 tablets 3-4 times per day between meals and dosing with other oral medicines for 2-3 weeks as a detoxification therapy. As required, the course of

therapy with White Coal® enteric sorbent at 2 tablets 3 times a day was repeated after a two-week interruption for an additional period of 2 weeks. Both groups of LC patients have been clinically observed to improve, which was manifest as decreased abdominal pain, dyspepsia, hepatosplenomegaly and astheno-neurotic syndrome [8]. Repeated biochemical tests in LC patients in course of treatment have demonstrated that the patients of the main group (those receiving the White Coal® enteric sorbent) have a distinct positive trend of biochemical parameters, characterised by a decrease to the upper limit of normal in total, direct and conjugated bilirubin ($p>0.1$), marking a trend towards normalisation of bilirubin metabolism. The patients of the main group were also found to have decreased levels of hepatic transaminases, such as ALT and AST (to the upper limit of normal), which indicated a significant relief of the cytolytic syndrome. It is telling that in parallel to the latter findings, the levels of excretory enzymes, such as alkaline phosphatase (AP) and gamma glutamyl transpeptidase (GGT) have been virtually normalised, which makes it safe to conclude that obstructive cholestasis has been eliminated in LC patients of the main group as well. Serum ammonia levels in LC patients of the main group (those receiving White Coal®), have also decreased to the upper limit of normal, which was evident of reduced toxic burden of this compound in organs and tissues, primarily the cerebral cortex. In course of treatment, serum levels of medium-weight molecules (MWM) have decreased in patients of the main group to the upper limit of normal, namely to 0.54 ± 0.03 mM, which indicated elimination of EMTS in these patients. When the influence of White Coal® on the biochemical parameters characterising lipid peroxidation levels and the activity of antioxidant protection was assessed, it was found that most patients in the main group (those receiving White Coal® enteric sorbent) had substantial improvements in the aforementioned tests; at the end of treatment period the findings of these tests were within the range of normal [8, 24-26].

The trends of investigational biochemical parameters were substantially weaker in control group patients, which received conventional therapy only; at the moment of treatment completion a fraction of patients had significant abnormalities of

investigational biochemical parameters, which indicated that biochemical improvements in non-enterosorption LC patients were less pronounced and full remission of hepatic parenchymal damage was not achieved in a majority of cases [25, 26].

It should be also noted that White Coal® enteric sorbent demonstrated positive outcomes in viral hepatic disease. Viral hepatitis is one of the most current health issues today. In the recent decades, Ukraine and other countries worldwide have faced a substantial rise in incidence of chronic viral hepatitis C (CVH-C), whose prevalence currently approximates that of an epidemic. The existing methods of pathogenetic treatment of CVH-C lack efficacy; therefore, in opinion of many experts, they call for further optimisation. Accumulation of various toxic substances in blood and other biological fluids of the patient is an important factor in pathogenetic mechanisms of CVH-C progression with further development of LC, which leads to the clinical and biochemical syndrome of metabolic toxicity with elevated serum MWM as a biochemical marker [5, 6]. At the same time, an important pathogenic role is played by accumulation of circulating immune complexes in the serum, which enhances liver tissue damage and causes progression of CVH-C. Given the importance of metabolic toxicity and accumulation of immune complexes, there is an increasing interest in enterosorption as a method for detoxification and elimination of these abnormal articles from the blood of CVH-C patients.

Another aspect of this study was evaluation of treatment outcomes in patients with low activity (LA) CVH-C. The object of the study was 2 randomised groups of LA CVH-C patients, matched in terms of age and exacerbation rate. The main group included 42 patients, which, in addition to their basic therapeutic protocol, received White Coal® enteric sorbent 2-3 tablets between meals 3 times a day for 10-14 consecutive days. The rationale was that the enteric sorbents based on super-finely dispersed silica dioxide (SiO_2), such as White Coal®, possess marked advantages over other classes of enteric sorbents (including porous sorbents), since they have high absorption activity, are not absorbed in the intestines (and therefore lack pharmacodynamics of their own) and are virtually complication-free. The control

group included 38 patients receiving conventional basic therapy in average therapeutic doses.

As demonstrated by clinical observations, elimination of clinical symptoms of exacerbated chronic disease process in hepatic parenchyma was achieved sooner in LA CVH-C patients of the main group (those receiving White Coal® in addition to their standard treatment) compared to their counterparts receiving basic therapy only. Thus, the elimination of the discomfort in the right upper quadrant occurred in the main group 6.4 ± 0.2 days earlier than in the control group, and bitter taste in the mouth disappeared in patients of the main group 2.2 ± 0.1 days earlier than in the control group. The patients with LA CVH-C with additional therapeutic exposure to White Coal® had more pronounced positive trends concerning the vegetative asthenic syndrome. Fatigue disappeared 4.4 ± 0.2 days earlier than in the patients receiving basic therapy only, appetite recovered in patients of the main group 3.7 ± 0.2 days sooner, malaise disappeared 2.5 ± 0.1 days sooner, sleep disturbances recovered 1.5 ± 0.2 days sooner, emotional instability disappeared 2.8 ± 0.3 days sooner and fatigue disappeared 3.7 ± 0.2 days sooner than in patients of the control group ($p < 0.05$ in all cases) [3]. In terms of laboratory findings, the White Coal® sorbent improves MWM levels and relieves immune toxicosis [3, 23]. Therefore, based on data obtained, inclusion of White Coal® enteric sorbent into the treatment protocol of LA CVH-C can be considered pathogenetically substantiated and clinically appropriate.

The efficacy of White Coal® has also been confirmed in treatment of hepatobiliary disease of combined viral and inflammatory origin. Thus, the clinical experience demonstrates CVH-C to be frequently combined with chronic non-calculous cholecystitis (CNCC), which is due to close anatomical and functional connections between the liver and the gall bladder (GB) [13]. The presence of comorbidities does not only cause more frequent exacerbations and aggravation of underlying disease, but also promotes further progression of such combined conditions. In order to assess clinical efficacy of White Coal® we have assessed 134 patients 22-52 years of age with moderately exacerbated LA CVH-C comorbid with chronic inflammatory GB disease. An important consideration leading the choice of

an enteric sorbent in such patients is the fact that silica dioxide in White Coal® is not porous and is super-finely dispersed and its sorption mechanism is based on electrostatic interaction with the sorbate molecules; besides that, the tablet with this sorbent additionally contains 200 mg of microcrystalline cellulose. Since the issue is a long-term medical use of enterosorption, adding cellulose has an important therapeutic role, since this substance prevents constipation in prolonged use sorbents. The following inclusion criteria were used in CVH-C patients: the presence of serum anti-HCV antibodies (detected by EIA at high concentrations), the presence of HCV RNA (detected with PCR at viral loads over 150×10^3 copies per 1 mL of serum and serum ALT not less than 4 times the upper limit of normal. For the purposes of this research, we formed 2 groups: the main group (68 patients) and the control group (66 patients). The randomised groups were matched in terms of patient gender, age, disease burden and viral load. Both groups received identical conventional treatment. However, the patients in the main group have additionally received White Coal® 3 tablets 3-4 times a day between meals and dosing with other oral medicines for 2-3 weeks. As required, after 2 weeks of interruption the course of treatment with White Coal® was repeated at 2 tablets 3 times for another 2-week period.

Clinical observations have demonstrated that using White Coal® as a part of multimodality therapy of patients with CNCC-comorbid CVH-C helps reduce the duration and severity of toxic symptoms, eliminate dyspepsia and pain and accelerates returning of liver to its normal dimensions. The ultrasound imaging monitoring provided evidence of a more rapid (compared to the control group) reduction of hepatomegaly, increase in homogeneous parenchyma in all regions of the liver, the disappearance of acute reactive GB wall oedema with normalization of its evacuation function. In general, the patients treated with White Coal®-inclusive combination therapy had shorter hospital stays. The analysis of changes in standard biochemical serum markers in patients of the main group showed a significantly faster reductions in bilirubin, transaminases, thymol test, LDH (with its normal fractioning restored), AP and GGT. Repeated laboratory tests at the end of treatment showed that most patients with CVH-C+CNCC in the main group had significantly

reduced MWM levels, parameters of adenylic blood system and serum immune complexes compared to baseline with many parameters virtually normal. At the same time control patients had substantially less pronounced positive trends of clinical and laboratory findings (including biochemical and immunological parameters), therefore at the end of treatment period the patients of this group still had significantly elevated serum levels of these parameters [13, 14, 15]. Therefore, as authors indicate, using White Coal® enteric sorbent as a component of multimodality treatment in patients with CVH-C+CNCC is both pathogenetically substantiated and clinically promising.

It is also important to mention the virtually complete elimination of oxidation stress and endogenous metabolic toxicity by using White Coal® enteric sorbent as a component of chronic hepatobiliary comorbidities in victims of Chernobyl nuclear accident. Treatment efficacy analysis has demonstrated that adding White Coal® to the basic therapy of LA CVH-C + CNCC in former rescue personnel that responded to Chernobyl nuclear accident restores the normal parameters of lipid peroxidation, improves the enzymatic portion of serum antioxidant system and restores the glutathione redox system. As for clinical presentation, White Coal® exceeds conventional treatment in terms of speed of recovery and restoration of hepatic function (as evidenced by standard biochemical tests) [1, 2].

The therapeutic efficacy of White Coal® in chronic viral hepatitis B in the setting of CNCC has been confirmed by decreased intensity of reactions with immune complexes. The positive therapeutic effect of this enteric sorbent was confirmed to combine with a more rapid recovery of liver function and improved general condition. No complications or adverse events have been noted when using White Coal® [7].

It is also expedient to employ White Coal® as a therapy for such inflammatory-necrotic liver disease as a nonalcoholic fatty liver disease (NAFLD), which includes hepatic steatosis (HS) and nonalcoholic steatohepatitis (NASH). Currently NAFLD is a ubiquitous chronic liver disease with high occurrence rates, which in terms of prevalence in adult populations is comparable to chronic viral hepatitis.

Clinical experience suggests that NASH is often combined with CNCC with this combination being an aggravating factor for the patient, including in terms of further evolution of steatohepatitis. Excessive activation of free-radical oxidation in the setting of compromised functional capacity of the antioxidant defence system is a universal contributing factor in inflammation and hypoxia, including those in NASH and CNCC. In addition to imbalanced pro-oxidant/anti-oxidant status, the general biological pathogenetic mechanisms include EMTS, which is an important factor in progression of NASH. Another important biochemical marker or abnormal process in the body is the C-reactive protein (CRP), which is considered an indicator of systemic inflammation in the body. Given the above, enterosorption as a corrective for impaired metabolic homeostasis, can be viewed as pathogenetic therapy in CNCC combined with NASH (CNCC + NASH).

To assess the efficacy of White Coal® in CNCC + NASH, we have assessed 74 patients aged between 28 and 59 years (36 males and 38 females), which at the time of assessment were in the phases of moderate exacerbation or unstable remission of NASH/CNCC. Chronic viral hepatitis B or C has been ruled out in the subjects by duplicate serum EIA tests for HCV/HBV markers. The patients with any history of alcohol and/or drug abuse (even episodic) have also been excluded. In order to meet study objectives, the patients were divided post-assessment into 2 groups, namely the main group (36 subjects) и control (38 subjects), randomized by gender, age and the frequency of NASH exacerbations over the last calendar year. In addition to conventional therapy, the patients in the main group received White Coal® enteric sorbent 2-3 tablets 4 times a day between meals or dosing with other oral drugs. The patients were instructed to take the product with a glass of drinking water. The duration of treatment was 15-20 days, depending on the outcomes achieved.

As a results of tests we have found that adding White Coal® enteric sorbent to the treatment protocol for patients with NASH + CNCC, there is a more rapid (as opposed to the control group receiving standard therapy only) regression of clinical symptoms suggestive of aggravation of chronic combined conditions of the liver and GB. The trend analysis for the functional condition of hepatobiliary system in course

of therapy has demonstrated that when White Coal® was used, the levels of bilirubin, transaminase activity and thymol test findings, as well as the overall achievement of clinical and biochemical remission of steatohepatitis and CNCC recovered sooner than when standard therapy was employed. Along with a faster achievement of complete full remission of NASH and CNCC, the use of White Coal® enteric sorbent restores the parameters of metabolic homeostasis, which were impaired at baseline. When the product is used in NASH + CNCC, the enterohepatic circulation of endotoxins and hepatocytic debris is interrupted, the anti-toxic functions of the liver are improved and serum reactive protein returns to normal. In the control group (where the treatment was performed with conventional therapies), the reductions in MWM, in products of membrane peroxidation (both intermediate products [diene conjugates] and terminal products [malondialdehyde]) and SRP in blood were significantly less substantial, which indicates that the signs of EMTS, as well as increased lipid peroxidation and systemic inflammatory response were still present in the body, albeit at lower levels than pre-treatment. The results obtained may serve as a rationale for inclusion of White Coal® silica enteric sorbent into therapeutic protocols in patients with combined chronic hepatobiliary disease, also manifest as NASH + CNCC, in exacerbations or in unstable remissions of chronic liver/GB inflammation [11].

Some authors noted the efficacy of White Coal® enteric sorbent in patients with NASH in the setting of CNCC and intestinal dysbiosis (IDB), keeping in mind that in a large proportion of cases this condition is accompanied by impaired patterns of intestinal microbiocenosis, which reflects the principle of mutual relationships in the body, that is, the damage sustained by one link of the system entails the respective changes in its other parts. Thus, clinical observations have demonstrated that using White Coal® as a component of treatment complex in patients with NASH in the setting of CNCC and IDB has facilitated more pronounced positive changes of clinical parameters and restoration of liver function; the pathogenetic implications included virtually complete normalisation of circulating immune complexes and their

fractional composition, which allowed the authors to consider using the White Coal® enteric sorbent a truly highly effective therapeutic [18, 19].

A number of clinical observations has demonstrated the efficacy of White Coal® in the therapy of NAFLD with concomitant obesity. The findings included normalisation of parameters of cellular immunity and antioxidant protection system in the patients additionally receiving this investigational product as a part of multimodality therapy [21].

Using White Coal® has also been proved expedient in NASH patients in the setting of Type 2 diabetes mellitus (DM). The trend analysis of clinical signs and biochemical markers of hepatic parenchyma allowed drawing a conclusion that most asthenic symptoms and hepatobiliary complaints disappear in the main group of patients already during the first 2 weeks of White Coal® therapy, whereas in the control group the aforementioned changes are noted 6-9 days later on an average. The clinical and biochemical remission lasting 1 year and more was documented in patients of the main group 2.11 more frequently than in patients of the control group [17].

It should be noted that the positive indirect influence of White Coal® on certain parameters of cellular immunity was found in patients with chronic GB/intestinal disease. Thus, when developing the principles of treatment for patients with CNCC combined with Irritable Bowel Syndrome (IBS) and IDB in the setting of secondary immunodeficiency, long-term use of White Coal® in such patients facilitates normalisation of cellular immunity (namely, elimination of T-lymphopenia, increasing the quantity of CD4⁺-lymphocytes, increasing the CD4 CD8 immunoregulatory index and the functional activity of T-lymphocytes (according to the findings of blastogenesis and PHA tests). Besides, inclusion of the modern silica-based White Coal® enteric sorbent into the protocol for CNCC combined with IBS and IDB in the setting of secondary immunodeficiency was found to facilitate reversal of clinical findings indicating exacerbation of such concomitant disease, as well as to restore normal microbial patterns in the intestines [20].

Therefore, the data obtained as a result of years of research and clinical observations allows us to assume that utilising the modern silica-based White Coal® enteric sorbent as a part of multimodality therapy for various acute, chronic and combined hepatobiliary disease, accompanied by pronounced endogenous toxicity, has substantial pathogenetic rationale and positive clinical perspectives.

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**Evaluation of the efficiency of enterosorbent White Coal[®]
in patients with the diseases of hepatobiliary system**

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Key words: enterosorption, silica, hepatobiliary system, treatment, efficiency

The efficiency of silica enterosorbent White Coal[®] is demonstrated in the treatment of such diseases of the hepatobiliary system as toxic and viral hepatitis, chronic non-calculous cholecystitis, nonalcoholic fatty liver disease.