EFFICACY OF COMBINATION THERAPY IN THE MANAGEMENT OF METABOLIC DISORDERS IN PATIENTS WITH TYPE 2 DIABETES MELLITUS AND FATTY LIVER DISEASE

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Objective. To evaluate the efficacy of different therapeutic approaches in patients with type 2 diabetes mellitus (T2DM) associated with fatty liver disease and to identify the most effective treatment combination for improving metabolic and hepatic parameters.

Materials and methods. The study included 85 patients with T2DM and fatty liver disease, comprising 39 women and 46 men aged 20–55 years, with a disease duration of 3–4 years. Clinical, laboratory, biochemical, and instrumental methods were used to assess treatment efficacy. The evaluation included blood and urinary glucose levels, lipid profile, insulin resistance indices, HbA1c, alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin levels, and liver ultrasonography with assessment of the degree of steatosis and fibrosis. Treatment efficacy was assessed based on clinical improvement, including resolution of major complaints, improvement in general condition, and normalization of laboratory parameters.

According to the treatment regimen, patients were divided into four groups. Group 1 (n=21) received standard therapy consisting of metformin, with sulfonylureas prescribed when indicated, together with the hepatoprotective agent Essentiale Forte. Group 2 (n=21) received standard therapy supplemented with black cumin seeds (Nigella sativa). Group 3 (n=21) received standard therapy combined with Protecto-Hepar. Group 4 (n=22) received combined therapy with both black cumin seeds and Protecto-Hepar in addition to standard treatment.

Results. The addition of black cumin seeds and Protecto-Hepar to standard therapy was associated with more pronounced clinical and laboratory improvement compared with standard treatment alone. The most substantial therapeutic effect was observed in patients receiving the combined regimen. In this group, clinical improvement was achieved in 95.4% of patients, while normalization of the main laboratory parameters occurred within 16 ± 1.0 days, demonstrating a shorter recovery period compared with standard therapy.

Conclusion. The findings indicate that the incorporation of black cumin seeds and Protecto-Hepar into standard therapy may improve the clinical and metabolic outcomes of patients with T2DM and fatty liver disease. The greatest therapeutic effect was observed with their combined use, suggesting that a comprehensive treatment strategy may be more effective in correcting metabolic and hepatic abnormalities in this patient population.