



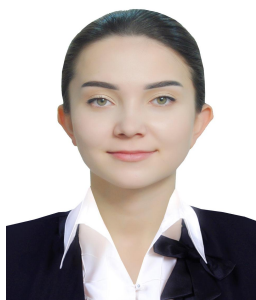
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MODERN APPROACHES TO ASSESSING TREATMENT EFFECTIVENESS IN PATIENTS WITH NON-ALCOHOLIC FATTY LIVER DISEASE ASSOCIATED WITH TYPE 2 DIABETES MELLITUS



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Abstract. The coexistence of type 2 diabetes mellitus (T2DM) and non-alcoholic fatty liver disease (NAFLD) represents a significant clinical and public health challenge due to their high prevalence and shared pathophysiological mechanisms. The present study aimed to evaluate the effectiveness of different therapeutic approaches and to develop comprehensive criteria for assessing treatment outcomes in patients with T2DM combined with fatty liver disease. A total of 85 patients aged 20–55 years were included in the study and divided into four groups depending on the treatment strategy. The findings demonstrated that combined therapy, including *Nigella sativa* and Protecto-Hepar in addition to standard treatment, resulted in a more pronounced improvement in clinical condition, biochemical parameters, and liver function compared to standard therapy alone. The highest treatment effectiveness (95.4%) and the shortest recovery period (16 ± 1.0 days) were observed in the combined therapy group. These results indicate that a pathogenetically justified



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combined therapeutic approach significantly improves treatment outcomes in this category of patients.

Keywords: Type 2 diabetes mellitus, NAFLD, fatty liver, Nigella sativa, hepatoprotection, metabolic syndrome, treatment effectiveness

2-TUR QANDLI DIABET BILAN ASSOTSIATSIYALANGAN NOALKOGOL YOG'LI JIGAR KASALLIGI BO'LGAN BEMORLARDA DAVOLASH SAMARADORLIGINI BAHOLASHNING ZAMONAVIY YONDASHUVLARI

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Annotatsiya. 2-tip qandli diabet va alkogolsiz yog'li jigar kasalligi birgalikda uchrashi ularning yuqori tarqalganligi hamda umumiy patofiziologik mexanizmlari tufayli muhim klinik va jamoat salomatligi muammosi hisoblanadi. Ushbu tadqiqotning maqsadi turli terapevtik yondashuvlarning samaradorligini baholash va 2-tip qandli diabet bilan alkogolsiz yog'li jigar kasalligi birgalikda kechadigan bemorlarda davolash natijalarini baholashning kompleks mezonlarini ishlab chiqishdan iborat edi. Tadqiqotga 20–55 yoshdagi jami 85 nafar bemor jalb qilinib, davolash strategiyasiga qarab to'rt guruhga bo'lindi. Olingan natijalar shuni ko'rsatdiki, standart davolashga qo'shimcha ravishda Nigella sativa va Protecto-Hepar qo'llanilgan kombinatsiyalangan terapiya klinik holat, biokimyoviy ko'rsatkichlar va jigar funksiyasining yaxshilanishida standart terapiyaga nisbatan ancha yuqori samaradorlik ko'rsatdi. Eng yuqori davolash samaradorligi (95,4%) va eng qisqa tiklanish muddati ($16 \pm 1,0$ kun) aynan kombinatsiyalangan terapiya guruhida kuzatildi. Ushbu natijalar patogenetik asoslangan kombinatsiyalangan davolash yondashuvi ushbu bemorlar toifasida davolash natijalarini sezilarli darajada yaxshilashini ko'rsatadi.

Kalit so'zlar: 2-tip qandli diabet, alkogolsiz yog'li jigar kasalligi, yog'li jigar, Nigella sativa, gepatoproteksiya, metabolik sindrom, davolash samaradorligi

СОВРЕМЕННЫЕ ПОДХОДЫ К ОЦЕНКЕ ЭФФЕКТИВНОСТИ ЛЕЧЕНИЯ У ПАЦИЕНТОВ С НЕАЛКОГОЛЬНОЙ ЖИРОВОЙ БОЛЕЗНЬЮ ПЕЧЕНИ, АССОЦИИРОВАННОЙ С САХАРНЫМ ДИАБЕТОМ 2 ТИПА

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Аннотация. Сочетание сахарного диабета 2 типа (СД2 — сахарный диабет 2 типа) и неалкогольной жировой болезни печени (НАЖБП — неалкогольная жировая болезнь печени) представляет собой значимую клинко-социальную проблему в связи с их высокой распространённостью и общими патофизиологическими механизмами. Целью настоящего исследования явилась оценка эффективности различных терапевтических подходов и разработка комплексных критериев оценки результатов лечения у пациентов с сахарным диабетом 2 типа в сочетании с неалкогольной жировой болезнью печени. В исследование были включены 85 пациентов в возрасте 20–55 лет, разделённые на четыре группы в зависимости от применяемой стратегии лечения. Полученные результаты показали, что комбинированная терапия, включающая Nigella sativa и Protecto-Hepar в дополнение к стандартному лечению, обеспечивает более выраженное улучшение клинического состояния, биохимических показателей и функции печени по сравнению со стандартной терапией. Наивысшая эффективность лечения (95,4%) и наименьшая продолжительность восстановления ($16 \pm 1,0$ дня) отмечены в группе комбинированной терапии. Полученные



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данные свидетельствуют о том, что патогенетически обоснованный комбинированный подход к лечению существенно улучшает исходы у данной категории пациентов.

Ключевые слова: сахарный диабет 2 типа (СД2), неалкогольная жировая болезнь печени (НАЖБП), жировой гепатоз, *Nigella sativa*, гепатопротекция, метаболический синдром, эффективность лечения

Introduction. Type 2 diabetes mellitus (T2DM) is a chronic metabolic disease characterized by insulin resistance, persistent hyperglycemia, and progressive β -cell dysfunction. In recent decades, the prevalence of T2DM has increased significantly worldwide, becoming a major public health concern. One of the most important comorbid conditions associated with T2DM is non-alcoholic fatty liver disease (NAFLD), which is currently considered the hepatic manifestation of metabolic syndrome [2,9]. NAFLD includes a wide spectrum of liver disorders ranging from simple steatosis to non-alcoholic steatohepatitis, fibrosis, and cirrhosis [4,11]. The coexistence of T2DM and NAFLD significantly worsens the clinical course of both diseases and increases the risk of cardiovascular complications, liver failure, and hepatocellular carcinoma [8,13]. The pathophysiological link between these conditions is based on insulin resistance, lipid metabolism disorders, visceral obesity, and chronic inflammation [14]. Therefore, the study of effective treatment strategies for this combined pathology is of particular importance.

Literature review and methodology. According to modern epidemiological studies, the prevalence of NAFLD among patients with T2DM exceeds 60–70%, which indicates a strong interrelation between these diseases [13]. NAFLD contributes to impaired liver function, including metabolic, detoxification, and synthetic processes, thereby aggravating the course of diabetes [1,12]. Furthermore, it has been shown that NAFLD itself may act as an independent risk factor for the progression of T2DM and its vascular complications [11]. Despite the availability of modern glucose-lowering drugs, standard therapy is mainly aimed at controlling blood glucose levels and does not always ensure regression of hepatic steatosis or prevention of fibrosis [3,5]. Recent studies demonstrate that certain pharmacological agents, including GLP-1 receptor agonists and SGLT2 inhibitors, have additional hepatoprotective effects and improve metabolic parameters [7,15]. The present study included 85 patients diagnosed with T2DM combined with fatty liver disease (39 women and 46 men aged 20–55 years with disease duration of 3–4 years). Diagnosis was based on clinical examination, laboratory tests (glucose levels, lipid profile including LDL and HDL, insulin resistance), biochemical markers (ALT, AST, bilirubin), glycated hemoglobin (HbA1c), and ultrasound assessment of hepatic steatosis and fibrosis. Patients were divided into four groups depending on the treatment approach. The first group received standard therapy including metformin, sulfonylureas when necessary, hepatoprotective agents, diet therapy, and physical activity. The second group received additional *Nigella sativa*, known for its antioxidant and anti-inflammatory properties. The third group received Protecto-Hepar, a hepatoprotective and detoxifying agent. The fourth group received combined therapy including both *Nigella sativa* and Protecto-Hepar alongside standard treatment. Treatment effectiveness was assessed based on clinical remission, normalization of laboratory parameters, and improvement in ultrasound findings.

Discussion. The results of this study confirm the importance of a комплексный подход к лечению пациентов с сочетанием T2DM и NAFLD. The observed improvements in patients receiving combined therapy can be explained by the synergistic effects of its components. *Nigella sativa* contains biologically active substances, including thymoquinone, which exhibit antioxidant, anti-inflammatory, and metabolic regulatory effects. These properties contribute to the reduction of oxidative stress and improvement of lipid metabolism. Protecto-Hepar, in turn, provides hepatoprotective and detoxifying effects, improves bile secretion, and enhances liver function. Its use leads to normalization of liver enzymes and improved metabolic processes. The combination of these agents with standard therapy allows not only effective glycemic control but also correction of



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hepatic dysfunction, which is often insufficiently addressed by conventional treatment alone. These findings are consistent with previous studies demonstrating the benefits of комплексной терапии in metabolic diseases [7,15].

Results. The analysis of treatment outcomes demonstrated a clear advantage of combined therapy over standard treatment alone. In the control group, clinical improvement was observed in 70.0% of patients, with normalization of clinical and laboratory parameters occurring within 28 ± 1.3 days. In the group receiving *Nigella sativa*, treatment effectiveness increased to 86.9%, and normalization occurred within 20 ± 1.2 days. In the group treated with Protecto-Hepar, improvement was observed in 90.0% of patients, with normalization within 19 ± 1.1 days. The most significant results were obtained in the combined therapy group, where 95.4% of patients showed clinical improvement, and normalization of parameters occurred within 16 ± 1.0 days. Patients in this group demonstrated faster resolution of clinical symptoms, including pain in the right hypochondrium, dyspeptic symptoms, weakness, and dry mouth. Biochemical indicators such as ALT, AST, glucose levels, and lipid profile showed more pronounced improvement in the combined therapy group compared to other groups. Importantly, no adverse effects were reported.

Conclusion and references. In conclusion, the findings of this study demonstrate that combined therapy including *Nigella sativa* and Protecto-Hepar alongside standard treatment significantly improves clinical and metabolic outcomes in patients with T2DM and fatty liver disease. This approach accelerates recovery, enhances normalization of biochemical parameters, and improves liver function. The proposed criteria for treatment effectiveness, based on a comprehensive assessment of clinical, laboratory, and instrumental indicators, allow for an objective evaluation of therapeutic outcomes and can be recommended for widespread clinical use, particularly in regions with a high prevalence of metabolic disorders such as the Khorezm region.

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