Evaluation of the therapeutic potential and safety of Al Hayat black cumin seed oil: an observational study

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Abstract

The purpose of this study was to investigate the therapeutic potential and safety of the use of Al Hayat black cumin seed oil. Descriptive and discrete statistical methods and frequency analysis were applied. There were 20 participants in total aged between 11 and 67 years, both men and women. The participants were divided into three subgroups, each receiving different doses of black cumin oil: 10 mg/kg, 20 mg/kg, and 30 mg/kg, respectively. Such parameters as general blood count, liver enzyme activities (aspartate aminotransferase and alanine aminotransferase), creatinine, and serum iron levels were analysed. A dose of 10 mg/kg was found to have no significant therapeutic or adverse effect. A dosage of 20 mg/kg demonstrated positive effects on platelet, immune cell, and creatinine values with no significant side effects. A dose of 30 mg/kg is not recommended for use due to the high risk of adverse reactions. The author also found no significant differences in the therapeutic effects and adverse reactions to black cumin oil that could be related to the gender or age of the participants.

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Key words: pharmacognosy, phytotherapy, immunomodulation, integrative medicine, thymoquinone.

Conflict of interest: the author declares no potential conflict of interest.

Funding: not applicable.

Ethics approval: the study was approved by the Ethics Commission of the Medical Educational Platform LLC "MedLit", No. 12455.

Patients' consent for publication: informed consent was obtained from all individuals included in this study.

Availability of data and material: the data supporting the findings of this study are available on request from the corresponding author

Received: 25 June 2024.
Accepted: 11 September 2024.
Early view: 9 October 2024.

Healthcare in Low-resource Settings 2024; 12(s2):12751
doi:10.4081/hls.2024.12751

Introduction

In modern medicine, the prospects for the use of plant-based remedies are greatly enhanced by public interest and the efforts of scientists. This interest is fuelled by the desire for more natural, organic ways to treat and prevent disease, as well as scientific discoveries that increasingly confirm the efficacy of plant extracts and compounds. Specifically, black cumin seed oil, extracted from the *Nigella Sativa* plant, is a prime example of a substance with a long history of use in traditional medicine due to its many potential therapeutic properties. Black cumin, used as a natural remedy in different cultures, has attracted the attention of scientists in the fields of biomedicine and pharmacology.[1] Despite promising anecdotal evidence and some preliminary studies suggesting a wide range of beneficial properties, from anti-inflammatory to antioxidant, rigorous scientific evaluation of black cumin oil's effects on concrete health parameters is still in its infancy. Scientific studies to investigate its effects may provide valuable information on its mechanisms of action, efficacy, and safety of use. Thus, despite its widespread use in traditional medicine and potential benefits, black cumin oil requires further research in the context of modern medicine.

Investigating the role of medicinal plants in controlling various diseases, including coronavirus infection, Ojah *et al*.[2] focused on ethnopharmacological approach, which can offer promising strategies for the development of new medicines. This approach emphasises traditional healing methods used across cultures and explores their potential for modern medicine. However, plants such as black cumin stay outside the main focus of such studies, which makes its investigation in this context particularly relevant. Regarding this issue, Khadka *et al*.[3] highlighted that in some countries during the COVID-19 pandemic, herbal medicine gained considerable popularity, especially in the context of disease prevention. The authors noted that many respondents recommended the use of medicinal plants for COVID-19 prevention, although qualitative studies on the efficacy of this approach are still lacking. In their work, Riaz *et al*.,[4] without focusing on black cumin, emphasised the significance of investigating phytometabolites for the development of new medicines. The scientists noted that phytobioactive compounds have potential in treating various diseases, making them promising candidates for clinical trials. Guo *et al*.[5] highlighted the high therapeutic potential of nanocrystals based on medicinal plants, especially in the context of improving the pharmacokinetics of active substances. This is crucial to improve the efficacy of pharmacotherapy and overcome the serious problems associated with the low solubility and bioavailability of a range of phytopreparations, including those that may include black cumin.

In the context of phytopreparation studies, Choudhury *et al*.[6] emphasise the significance of careful control and monitoring of such products. This is to ensure their safety and efficacy, considering potential risks and side effects. Controls should include standardisation of ingredients, screening for toxins and other potentially harmful components, and clinical studies to confirm claimed

properties. This approach ensures that patients get the maximum benefit from phytopreparations without compromising their health.

Thus, the purpose of this study was to collect and analyse empirical data to understand the effect of black cumin oil consumption on human body at different dosages. The main objectives of the research are the following: i) to figure out the ideal dosage to enhance effectiveness while limiting negative effects; ii) to assess whether factors such as age and gender influenced the therapeutic response to black cumin oil.

Materials and Methods

The statistical data were obtained by analysing medical records, including patients' medical histories, as well as the results of laboratory testing methods, including general blood counts, analysis of liver enzyme activities such as Aspartate Aminotransferase (AST) and Alanine Aminotransferase (ALT), creatinine, and serum iron levels. These indicators were chosen as the main criteria for assessing the effects of the medicine on the participants' bodies.

There were 20 participants in total who were selected according to predetermined inclusion and exclusion criteria. Participants were informed about the purpose and methods of the research and provided their informed consent to participate. Of the 20 participants initially selected, 18 participants reached the end of the study. Two participants discontinued their participation for personal reasons. Only the results of those participants who fully completed the study were used for data analysis. Participants' ages ranged from 11 to 67 years (mean age: 35.33 years, mode: 36 years, median: 34.5 years). Both males and females took part in the examination, the data regarding the sampling frame by gender is presented in Figure 1.

To structure the sample, optimise the results, and to better understand the health effects of black cumin oil, the author divided the participants into three subgroups. Each of these subgroups received a different specific dose of black cumin oil, namely 10 mg/kg, 20 mg/kg, and 30 mg/kg respectively. The structure of the study group according to the medication dosage used is presented in Figure 2. This separation allowed for a differentiated analysis of the effects of different doses of black cumin oil on the body, which enabled a more accurate determination of its efficacy and safety.

The dosage was allocated based on perceptions of safe and potentially effective levels of black cumin oil consumption.[7,8] The main objective of this approach was to determine the best dosage that would maximise efficacy while minimising the risk of side effects. Each group of participants took a corresponding dosage of black cumin oil for 15 days, during which time their health status was monitored regularly.

Using normal venepuncture techniques, participants' blood samples were drawn into vacuum tubes containing ethylenediaminetetraacetic acid (EDTA)for a complete blood count and serum separator tubes for biochemical analysis. To guarantee adequate mixing, samples were gently flipped eight to ten times as soon as they were collected. To preserve cellular integrity, EDTA tubes for haematology were examined four hours after collection and kept at room temperature (20-25°C). In order to separate the serum, serum separator tubes were centrifuged at 3000g for 10 minutes after being left to clot at room temperature for 30 minutes. To maintain the stability of the analytes, the serum was aliquoted into cryovials and kept at -80°C until analysis, which was carried out 30 days after collection. Every sample had a unique label applied to it, and regular safety procedures were followed when handling it. All storage units had temperature logs kept in order to guarantee constant conditions. Excluded from analysis were samples exhibiting haemolysis or lipemia, in order to avoid influencing test outcomes.

All of the laboratory equipment underwent stringent calibration and quality control procedures to guarantee the dependability and accuracy of experimental results. Automated biochemistry and haematology analysers were validated with multi-level control materials and daily calibrated using calibrators supplied by the manufacturer. The Clinical Laboratory Improvement Amendments (CLIA) recommendations were followed in setting the acceptance criteria and creating calibration curves for each analyte. Every piece of equipment had a maintenance journal that recorded both routine maintenance and any necessary corrective action. Any equipment that did not meet performance standards was taken out of service right away and left to be fixed or recalibrated.

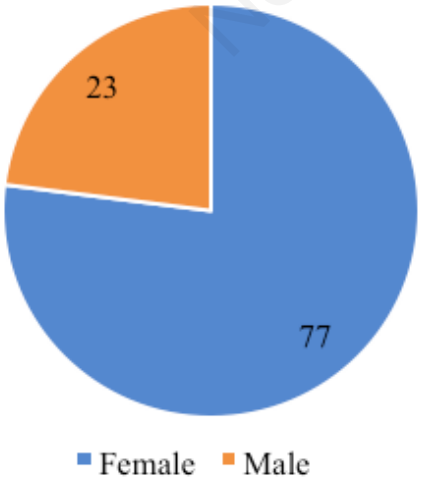

Figure 1. Structure of the study group by gender. Source: compiled by the author.

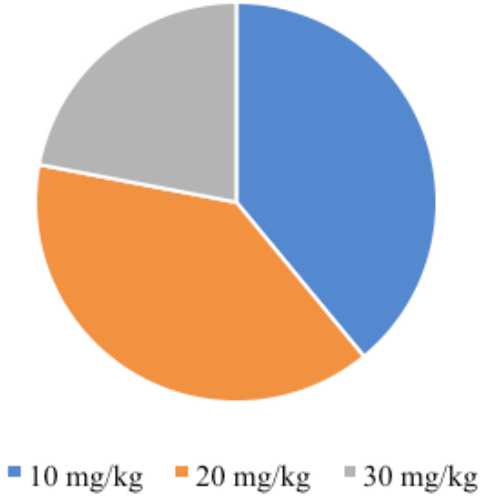

Figure 2. Structure of the study group according to the medication dosage used. Source: compiled by the author.

The investigation predominantly used descriptive and discrete statistical methods and cluster analysis. Descriptive statistics were used to provide an overview of the data, including mean values, standard deviations, and ranges for key variables such as blood counts and liver enzyme activities. This provided a basic understanding of the distribution and underlying trends in the data. Discrete statistics were used to determine statistically significant differences between groups of participants receiving different dosages of black cumin oil. This method helped to assess whether different dosage of the medication affected the health indicators under study to a statistically significant degree. Cluster analysis was used to identify groups of participants with analogous treatment response patterns. This provided a greater understanding of individual differences in treatment response and helped to identify potential subgroups of participants who respond best to certain dosages.

Results

Within the sample provided, it was important to observe how even a minimal dose of black cumin oil could affect various biochemical and physiological parameters such as blood counts and liver enzyme activities. This dose, 10 mg/kg, was chosen as the starting point of the research based on the assumption of its safety and potential efficacy. It was assumed that such a dose could provide the minimum therapeutic effect while reducing the risk of undesirable adverse reactions. The results of monitoring of the studied indicators, both preliminary and at the end of the study, are presented in Table 1. When analysing these results, it was recorded that the effect of the medication was moderated. Minimal changes in clinical parameters indicate insignificant effect of this dosage on the biochemical profile of the organism. This can be interpreted as a lack of overt therapeutic activity or as achieving only a marginal effect that is on the edge of statistical significance. A comparable pattern was observed in the context of side effects, with very few or no side effects. These results may indicate a high safety profile of the medication at the indicated dosage, which, at the same time, does not make it potentially suitable for long-term use or as a component of complex therapy, due to the lack of clinically significant results. However, the absence of significant side effects and minimal therapeutic effect may also indicate that the dose is insufficient to achieve the desired therapeutic effect. It is possible that such a dosage cannot activate the mechanisms responsible for the pharmacological action of the medication, and therefore cannot fully reveal the potential of the active components of black cumin oil. These analyses of the laboratory results of this subgroup provided the basis for further investigation of higher doses to determine the threshold at which a significant therapeutic effect comparable to an appropriate level of safety is observed. The study of minimal effects and adverse reactions is also important for the development of a complete medication profile. This is particularly relevant when developing dosages for clinical use that consider individual patient characteristics and the possibility of an individualised treatment approach. Considering that the previous dosage demonstrated only minimal effects on participants' biochemical parameters and no significant side effects, the second subgroup provided a better opportunity to investigate whether the increased dosage would result in more noticeable health effects. The corresponding results are presented in Tables 2 and 3. It was found that increasing the dosage of black cumin oil to 20 mg/kg resulted in markedly positive changes in the clinical parameters of the participants.

The most significant trend was the normalisation of platelet levels, which may indicate improved blood coagulation and reduced risk of haemorrhagic complications. Furthermore, mobilisation of immune cells was observed, which is reflected in the white blood cell count in the blood, suggesting an increase in the body's immune response. Another indicator that underwent changes as a result of the increased dosage was creatinine levels, which also normalised, which may indicate a positive effect on renal function. Interestingly, in one case studied, the use of black cumin oil at this dosage optimised the significantly elevated liver enzymes ALT and AST, which may be related to both individual patient characteristics and the general pharmacological properties of the medication. Importantly, increasing the dose to 20 mg/kg was not accompanied by the occurrence of side effects. This fact suggests that this dosage is not only safe, but also probably optimal in terms of efficacy/safety ratio. Complementing the information presented above, attention should also be given to considering the therapeutic efficacy of a 30 mg/kg dose of black cumin oil. Considering the positive effects of the previous dose of 20 mg/kg on platelet counts, immune activity and creatinine levels, there was

Table 1. Mean values of laboratory results in patients from the subgroup treated with the medication at a dosage of 10 mg/kg.

Blood parameter	Preliminary results*	Results after 15 days of use*
Liver enzymes, creatinine, and serum iron values		
Creatinine, μmol/l	52	54.2
ALT, IU/l	12.6	13
AST, IU/l	16.5	14.4
Iron level, μmol/l	10.9	13.6
General clinical parameters		
Haemoglobin, g/l	108	118
Erythrocytes ($\times 10^{12}$/l)	4.2	4.3
Haematocrit, %	37.2	37.4
Mean corpuscular volume (MCV), fl	88.5	90.2
Mean corpuscular haemoglobin concentration (MCHC), g/dl	320	328
White blood cells ($\times 10^9$/l)	6.1	6.2
Neutrophils ($\times 10^9$/l)	4.2	4.1
Lymphocytes ($\times 10^9$/l)	1.3	1.5
Platelets ($\times 10^9$/l)	223	230

Note: IU/l – international units per litter; *p>0.05. Source: compiled by the author.

a legitimate interest in whether further dose increases could result in enhanced therapeutic effects or side effects. This phase of the research evaluated the efficacy and safety of black cumin oil when administered at higher doses, which is critical to determining its maximum tolerated dosage. When the results of laboratory methods were analysed on participants who used the medication at a dosage of 30 mg/kg, it was found that this dose did not lead to the expected improvement in therapeutic outcomes. Specifically, there was no further improvement in blood parameters, which could indicate a more pronounced beneficial effect on physiological body functions, compared to the group receiving 20 mg/kg.

A significant and worrying consequence of the increased dosage was the occurrence of pronounced side effects. Complaints of decreased sleep quality, decreased general well-being of participants, and non-specific gastrointestinal disorders such as discomfort, bloating, and stool disturbances were observed. These symptoms may indicate that this dosage exceeds physiologically acceptable intake rates for vegetable oils, resulting in undesirable body reactions.[9,10] These side effects are probably not directly related to the pharmacological properties of black cumin, but rather result from the specific effects of plant-based oils in general when consumed in excess. Such reactions may be caused by both the general properties of fatty acids and the presence of certain components (such as thymoquinone, alkaloids like nigellicine, and saponins), which in large quantities may interfere with the normal functioning of the digestive system and affect metabolism.[11-13] Thus, although the previous dosage of 20 mg/kg showed potential optimality, a further dose increase to 30 mg/kg did not improve the therapeutic results but provoked adverse reactions. This emphasises the need for careful dose balancing to maximise benefits while minimising risks. The study also analysed possible factors that could influence the therapeutic efficacy of the medication. Specifically, attention was paid to participant characteristics such as gender and age. Analyses of the data collected, which included a wide range of age groups and representation of both sexes, revealed no significant differences in response to therapy that could be attributed to the sex or age of the patients. Analysis of the available data made it possible to verify that the therapeutic effect of black cumin oil appears to be stable and homogeneous among the entire sample, with no apparent dependence on the parameters mentioned. In

Table 2. Mean values of laboratory results in patients from the subgroup receiving the medication at a dosage of 20 mg/kg.

Blood parameter	Preliminary results*	Results after 15 days of use*
Liver enzymes, creatinine, and serum iron values		
Creatinine, μmol/l	48	40.4
ALT, IU/l	28.2	16
AST, IU/l	40.1	14.2
Iron level, μmol/l	13.2	16.3
General clinical parameters		
Haemoglobin, g/l	123	133
Erythrocytes (×10^{12}/l)	4.32	4.46
Haematocrit, %	38.6	39
MCV, fl	86.4	89.2
MCHC, g/dl	334	362
White blood cells (×10^{9}/l)	6.3	5.8
Segmented neutrophils (×10^{9}/l)	3.9	3.6
Lymphocytes (×10^{9}/l)	1.42	1.64
Platelets (×10^{9}/l)	276	296

Note: *p>0.05. Source: compiled by the author.

Table 3. Mean values of laboratory results in patients from the subgroup receiving the medication at a dosage of 30 mg/kg.

Blood parameter	Preliminary results*	Results after 15 days of use*
Liver enzymes, creatinine, and serum iron values		
Creatinine, μmol/l	44	43
ALT, IU/l	6.3	9.7
AST, IU/l	9.2	8.2
Iron level, μmol/l	9.6	12.8
General clinical parameters		
Haemoglobin, g/l	112	121
Erythrocytes (×10^{12}/l)	3.82	4.26
Haematocrit, %	36.4	37.6
MCV, fl	79	83
MCHC, g/dl	322	334
White blood cells (×10^{9}/l)	5.1	4.8
Neutrophils (×10^{9}/l)	3.5	3.4
Lymphocytes (×10^{9}/l)	2.1	2.7
Platelets (×10^{9}/l)	312	336

Note: *p>0.05. Source: compiled by the author.

none of the subgroups analysed were gender or age differences observed to make adjustments to the clinically significant response to the medication. The lack of variability in the efficacy of the medication according to gender and age may indicate its wide potential range of use and provides a basis for a better understanding of its mechanisms of action. This may also indicate that the medication has versatile properties that make it suitable for a diverse patient population, which is particularly significant in the context of personalised medicine.

The author decided to include several pregnant and breastfeeding women in the sample, which represents a prominent aspect in assessing the safety and efficacy of the medication in these special patient groups. Despite the potential risks associated with the use of any medication during pregnancy and lactation, no features or undesirable effects specific to these groups were identified. However, the use of black cumin oil or any other preparations in pregnant and lactating women requires extra caution.[14-16] Pregnancy and lactation period are accompanied by a range of physiological changes in a woman's body, which may affect the metabolism of medications and their pharmacokinetics.[17,18] Furthermore, it is vital to consider the potential risk to the developing foetus or infant, as some substances may penetrate the placental barrier or be excreted with breast milk.[1] Therefore, even though there were no adverse effects identified in this investigation, it is critical that care be taken when prescribing dosages and monitoring the health of pregnant and breastfeeding women taking black cumin oil. This requires an individualised approach and careful assessment of the balance of potential benefits and risks for each woman and her baby. It is recommended that such decisions be made in conjunction with a qualified medical professional, based on a complete clinical picture and considering all the individual characteristics of the pregnant or breastfeeding woman.

In the context of the findings, it is also necessary to mention some of the challenges and limitations that accompanied the execution of the study. Although the it has provided valuable preliminary data, it has a range of specific limitations that affect the interpretation and generalisation of its findings. Firstly, this is an observational study conducted by a single researcher. This approach can introduce subjectivity into the process of data collection and analysis, as well as in the interpretation of the findings. Lack of independent observation and validation can lead to possible misleading conclusions, making the results less valid and reliable. The second significant limitation is the sample size. Using a small number of participants reduces the statistical significance of the research, which may limit the ability to detect real effects or differences. Moreover, there was no control group or randomised allocation of participants, which is a key element in establishing causality. The absence of a control group means that it is not possible to determine with certainty whether the observed changes were the result of the medication or caused by other factors. Randomisation helps to eliminate systematic errors and bias, providing more reliable and objective results. Considering these limitations, the findings of the current study should be regarded as preliminary and interpreted with caution. Additional studies, including larger controlled clinical trials, are needed to provide a more accurate and generalised picture, which may confirm or refute the initial observations and conclusions.

Discussion

In the context of the current research, it is crucial to make a comparative analysis with contemporary studies conducted by foreign authors. Such a comparison will not only enrich the understanding of the topic at hand, but will also identify potential gaps in knowledge, as well as identify areas for future studies. Comparison with international studies provides an opportunity to establish the extent to which the findings of the current investigation are consistent with global scientific evidence. This will also help to assess the universality and applicability of the findings on a larger scale. International studies may reveal various aspects of black cumin oil use, including its pharmacological properties, mechanisms of action, potential therapeutic applications and possible side effects, which may not have been fully covered in the current work.

Thus, A. Zarrouk *et al*.[19] addressed the question of the composition of black cumin and its oil. In their paper, the researchers suggested that black cumin and its derivatives, including black cumin oil, have a wide range of beneficial properties, making them promising for the development of medicines to combat various diseases. The scholars focused on the rich composition of black cumin seeds, which includes proteins, fats, carbohydrates, fibre, and inorganic mineral compounds. They also considered the composition of black cumin oil, which contains both saturated and unsaturated fatty acids, including linoleic, oleic, dihomolinoleic, and eicodadiene acids. Furthermore, the oil contains alkaloids (nigellicins and nigelladine), saponins, tocopherols, phytosterols, flavonoids, and essential oil, as well as quinone components, including thymoquinone.[20] These components account for the wide range of therapeutic properties of black cumin oil, making it potentially useful in the treatment of a variety of diseases. Despite the avoidance of detailed analyses of individual clinical cases, the results of the cited work effectively complement the present study in terms of researching the components of the investigated substance and, consequently, the mechanisms of their effects on the human body.

A. Hannan *et al*.[21] also considered possible mechanisms of the effect of black cumin oil on the human body. The researchers noted that black cumin and its key component, thymoquinone, have immunomodulatory properties. Ethanolic extract of black cumin was also found to increase the population of macrophages and stimulate the phagocytic activity of their three types. The antioxidant properties of black cumin also contribute significantly to its therapeutic effects. Black cumin is a potential source of natural antioxidants, lowering levels of reactive oxygen species and increasing the activity of antioxidant enzymes such as superoxide dismutase and catalase, as well as molecules such as glutathione.[22] The researchers found a considerable increase in total antioxidant activity in the blood and a decrease in malonic dialdehyde levels on the background of black cumin seed supplementation. In addition, black cumin and thymoquinone have anti-inflammatory properties. Thus, freshly extracted black cumin oil reduced interleukin-6 levels in human preadipocytes, whereas oil stored for some time reduced interleukin-1beta levels. Consequently, although the paper does not cover aspects of the effects of the substance on some functions, specifically the liver, it greatly enriches the understanding of the pathogenetic mechanisms of the effects of the studied substance on the human body.

E.M. Yimer *et al*.[23] considered black cumin as a basis for the development of medicines for a wide range of diseases. The researchers noted that due to its wide range of properties, black cumin could serve as a substrate for medicines in the fields of neurology, oncology, cardiology, immunology, and other areas of medicine. Specifically, the authors highlight its potential application in the treatment of neurological disorders such as Alzheimer's, Parkinson's, and epilepsy, as well as cancers including breast and

prostate cancer.[24] The researchers also highlighted the antioxidant, antimicrobial, and anti-inflammatory properties of black cumin, making it a promising candidate for the development of new medicines. However, scientists have ignored the issue of side effects of the black cumin-based remedies in question.

Some researchers, such as M.S.K. Ermumcu and N. Şanlıer[25] considered the therapeutic potential of black cumin through the lens of, as they suggested, its most biologically active component, thymoquinone. The scholars emphasised that the use of black cumin-based preparations holds great promise in diabetes therapy. Thymoquinone and other components contribute to optimising glucose control, mainly by stimulating the metabolism of carbohydrates and reducing their concentration in the blood.[26,27] Thymoquinone along with some other components of black cumin extract stimulates insulin production, improves energy metabolism in mitochondria, and has an indirect hepatoprotective effect. It also affects the functioning of membrane receptors and improves their sensitivity to insulin. Black cumin, specifically, effectively inhibits gluconeogenesis – a key factor in the development of hyperglycaemia in diabetic patients, by reducing the activity of enzymes involved in this process.[28] Black cumin extract restricts glucose absorption and blocks its transport systems. Thymoquinone also exerts a protective effect on pancreatic β-cells by preventing oxidative stress.[29,30] Black cumin and thymoquinone have properties that promote weight loss and improve the lipid profile in diabetic patients, as evidenced by a reduction in body weight sometime after starting to take the preparations.[31] Thus, this study provides valuable additions to the investigation of the effects of black cumin-based medicines in the treatment of a diabetes mellitus.

J.V. Thomas *et al*.[32] conducted a randomised double-blind placebo-controlled study with an analogous purpose. The scholars evaluated the safety of using black cumin oil at a dose of 200 mg/day for 90 days. Seventy participants were involved. Both biochemical and general clinical parameters were analysed, and side effects were recorded. No serious side effects or significant changes in haematological parameters were reported. There were also no significant changes in biochemical parameters related to liver function (ALT, AST) and renal function (serum creatinine and urea). However, lipid profile analysis showed a significant ($P<0.05$) decrease in total cholesterol, low-density lipoprotein, very low-density lipoprotein, and triglycerides. Thus, the cited study differed slightly from the results obtained in the present one: the discrepancy primarily concerns the presence of side effects and the focus of the therapeutic action of the medicine.

N. Salaria *et al*.[33] directly addressed the safety of the use of black cumin derivatives. The researchers emphasised that the consumption of *N. sativa* at a dosage of 5 ml/day for 26 days caused no significant adverse effects on hepatic, renal, or gastrointestinal functions. It was also found that patients with hepatitis C who took black cumin oil capsules experienced epigastric pain and hypoglycaemia. In isolated cases, consumption of oil and ground seeds resulted in increased levels of AST, ALT, and alkaline phosphatase. However, no significant changes in kidney or liver function were found in people with diabetes who took black cumin at doses of 1, 2, and 3 g/day for 3 months. The scholars noted that some people may experience allergic reactions when using black cumin oil, such as allergic contact dermatitis when applied topically. Such cases have been reported in patients using black cumin oil externally. Thus, the paper extends previous findings to cover a wider range of medication dosages. However, researchers have neglected to investigate the mechanisms of side effects.

Thus, the studies of foreign colleagues devoted to the investigation of the therapeutic efficacy and safety of black cumin oil were reviewed. The analysis of the obtained results helped to supplement and expand the ideas about the main pharmacological effects of this phytopreparation, as well as to identify some differences in the nature and severity of its action. Comparison of the data obtained in the present study with the findings of foreign studies is of great value for a more complete understanding of the therapeutic and adverse potential of black cumin oil in different conditions of its application.

Conclusions

By interpreting the findings, it is possible to conclude on the therapeutic effects and side effects of black cumin oil. At low dosages of the medicine, a restrained effect on the biochemical profile of the organism was observed, indicating that there was no apparent therapeutic activity or only a marginal effect. There were few or no side effects in this case, which may indicate a high safety profile of the medication at these dosage levels. At the dosage of 20 mg/kg, marked positive changes in clinical parameters were observed, including normalisation of platelet levels. Creatinine levels also normalised, which may indicate a positive effect on renal function. No side effects were observed at this dosage, making it potentially the best dosage in terms of efficacy/safety ratio. However, when the dose was further increased to 30 mg/kg, no further improvement in clinical parameters was recorded, but pronounced side effects appeared, including complaints of impaired sleep quality, decreased general well-being, and gastrointestinal disturbances. This indicates that the dosage exceeds physiologically acceptable intake rates for vegetable oils.

According to the results, the therapeutic effects of black cumin oil appeared to be stable and homogeneous among the different groups of participants. This indicates its wide potential range of applications and versatile properties, making it suitable for a diverse patient population. Pregnant and breastfeeding women were also included in the study, which represents a prominent aspect in assessing the safety and efficacy of the medication in these special patient groups. However, despite no adverse effects identified, extra caution is required when using black cumin oil in pregnant and lactating women. Notably, clinical trials with more participants from different demographic groups are needed to increase the validity of the results. This will help to assess the efficacy and safety of black cumin-based products more accurately. Research vectors in this area should focus on better understanding the biochemical and molecular mechanisms underlying the therapeutic action of black cumin, which will provide a better insight into its effects and develop more effective dosage forms.

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