Original Article

Investigation of the Effect of Topinambur Extract on Cholesterol Levels

Alina Sergeevna Shahova[1], Evgenii Yurevich Chmutov[2], Amina Ramazanovna Shkhanokova[2], Nikita Vitalievich Cherevatov[1*], Azhbike Emzathanovna Kokozova[1], Aminat Visingereevna Isaldibirova[1], Svetlana Vitalyevna Oganyan[1], Ibragim Ilyasovich Elmurzaev[1]

[1]Department of Therapy, Faculty of Medicine, Stavropol State Medical University, Stavropol, Russia. [2]Department of Therapy, Pediatric Faculty, North Ossetian State Medical Academy, Vladikavkaz, Russia.

Abstract

This study aimed to investigate the impact of concentrated topinambur extract (CTE) on low-density lipoprotein cholesterol (LDLC) and high-density lipoprotein cholesterol (HDLC) levels in individuals suffering from atherogenic dyslipidemia. The control group adhered to a standard low-calorie diet throughout the treatment period. Meanwhile, the main group followed a modified version of the same diet, incorporating 100 mL of CTE. Our research into the use of CTE in treating dyslipidemia yielded valuable data. The findings indicate that this treatment option is well-tolerated and comparable to standard diet therapy in terms of weight loss. Moreover, we observed a positive impact on blood lipid profile. There was a statistically significant reduction in LDLC levels, while HDLC remained unchanged. This suggests a targeted effect on cholesterol levels without compromising overall cardiovascular health. Furthermore, there were no changes in liver function markers such as aspartate transaminase (AST), alanine aminotransferase (ALT), creatinine, or uric acid among patients receiving CTE.

Keywords: Diet, Atherogenic dyslipidemia, Cholesterol, Topinambur

Introduction

Every year in Europe, more than 4 million people die from cardiovascular diseases (CVD) [1]. Most of these diseases are of atherosclerotic origin [2]. For instance, mortality from CVD diseases in the Russian Federation in 2023 amounted to 624.5 cases per 100 thousand population [3].

The development of CVD is associated with risk factors (RF), among which there are modifiable (changeable) and unmodified (immutable) [4]. In turn, the basis for the prevention of CVD of atherosclerotic genesis are healthy lifestyle and diagnosis of RF such as low-density lipoprotein cholesterol (LDLC) and blood pressure (BP), as well as normalization of body weight [5]. Atherogenic dyslipidemia (hyperlipidemia) includes a triad of metabolic disorders: an increased concentration of LDLC in the blood, a decrease in high-density lipoprotein cholesterol HDLC, an increase in triglycerides (TG) [6, 7].

A special place is occupied by the residual risk of cardiovascular complications in patients receiving optimal statin therapy. This is fair for a group of patients that can not achieve the target values of LDLC, despite therapy with the maximum dose of statins and other drugs [8]. Most often, such residual dyslipidemia occurs among patients with obesity or overweight [9, 10]. This is associated not only with the presence of gross metabolic disorders but also with factors limiting the use of maximum doses of statins, such as non-alcoholic fatty liver disease and steatohepatitis [11].

Among patients receiving optimal statin therapy, a special focus is on the residual risk of cardiovascular complications. This group of patients fails to achieve the target values of LDLC despite treatment with the maximum dose of statins and other medications [8]. Residual dyslipidemia is most prevalent among individuals with obesity or overweight [9, 10]. This is attributed not only to severe metabolic disorders but also to factors that limit the use of maximum doses of statins, such as non-alcoholic fatty liver disease and steatohepatitis [12, 13]. This group of patients requires innovative strategies to enhance the efficacy of lipid-lowering treatment [14]. Among these strategies, non-pharmacological interventions, particularly dietary modifications, hold significant promise [15, 16]. It has been proven that against the background of complex therapy with a change in diet, it

Address for correspondence: Nikita Vitalievich Cherevatov, Department of Therapy, Faculty of Medicine, Stavropol State Medical University, Stavropol, Russia.
bucky99@yandex.ru

How to cite this article: Shahova AS, Chmutov EY, Shkhanokova AR, Cherevatov NV, Kokozova AE, Isaldibirova AV, et al. Investigation of the Effect of Topinambur Extract on Cholesterol Levels. Arch Pharm Pract. 2024;15(4):53-57. https://doi.org/10.51847/DVe6FN5cVU

is possible to achieve a significant decrease in the content of atherogenic lipids or eliminate the causes that prevent the appointment of maximum doses of drugs [17].

Numerous studies show pronounced changes in LDLC levels in response to diet therapy and the use of medications [18, 19]. These findings highlight the importance of comprehensive treatment approaches that combine lifestyle modifications, such as dietary changes, with pharmacological interventions [20]. However, despite the availability of effective treatments, a significant proportion of patients still struggle to achieve optimal lipid profiles [20]. This underscores the need for further research into alternative strategies that can help address residual dyslipidemia and reduce cardiovascular risk in these individuals Thus, in the complex of measures aimed at the treatment of this category of patients, the first place belongs to the search for new methods of dietary reduction of atherogenic dyslipidemia.

Concentrated topinambur extract (CTE) contains inulin, vitamins B1-B12, E, P, and H, as well as amino acids, micro- and macronutrients, and natural sugars [21, 22]. Taking into account the composition of the CTE, it seems advisable to study its effects within the framework of a controlled study. Therefore, this study aimed to assess the effect of inclusion in the diet of CTE on the level of atherogenic lipids in patients with dyslipidemia [21-23]. This approach would allow for a comprehensive evaluation of the potential benefits and risks associated with the use of CTE. The results of such a study could contribute to the development of more effective and safe treatment options for patients with dyslipidemia.

Materials and Methods

The patients were divided into experimental and control groups as presented in **Table 1**.

Table 1. Characteristics of the participants selected for the study.

Index	Groups	
	Experimental	Control
Number of patients	20	20
Average age, years (M±SD)	57.5±3.5	56.1±3.2
Man, %	10 (50%)	10 (50%)
Women, %	10 (50%)	10 (50%)
LDLC level, mmol/L (M±SD)	4.1±0.83	3.7±0.98

During the entire course of treatment, patients in the control group received a standard low-calorie diet with a decrease in table salt (≤ 2.5 g per day), animal fats (less than 10% of the daily caloric content of the diet), sugar (≤ 10 g per day), cholesterol-containing products, and extractives. During the course of inpatient treatment, patients in the main group were provided with a modified version of the standard low-calorie diet, which included 100 mL of CTE.

The nutritional value of the CTE is presented in **Table 2**.

Table 2. Nutritional value of the CTE

Carbohydrates, %	Proteins, %	Organic acids, %	Energetical value, kcal
65.0	3.5	1.0	277.0

Table 3 shows the characteristics of the diets of the patients.

Table 3. The average daily content of nutrients and the energy value of the standard diet and experimental diet with the CTE.

Diet	Proteins, g per day	Fats, g per day	Carbohydrates, g per day	Energetical value, kcal per day
Standard diet	84.8–90.0	59.6–63.3	200.8–213.2	1678–1781
The proportion of daily caloric intake	20%	31%	49%	–
Experimental diet	88.3–93.5	59.6–63.3	265.8–278.2	1955–2058
The proportion of daily caloric intake	18%	27%	55%	–

As can be seen from **Table 3**, the addition of CTE to the diet preserves the classical distribution of macronutrients in the diet. At the same time, the addition of CTE to the diet was accompanied by the exclusion of additional sugars, which did not significantly increase the proportion of simple carbohydrates in the diet [24-26].

The administration of medicines was carried out in accordance with clinical recommendations for diseases of a therapeutic profile [27, 28]. All therapy was continued during the follow-up period at the same doses. In this regard, the groups were comparable in this indicator. All patients were told about the composition, method of application, and expected therapeutic and preventive effects of the applied diets, and a voluntary consent was signed to participate in the study. Notably, the inclusion of CTE in the diet was well tolerated, and there were no refusals to participate in the study.

Statistical data processing was carried out using the STATISTICA 12 software. The indicators were given as the mean (M) and standard deviation of the mean (SD) for indicators that demonstrated a normal distribution, and the median (Me) and the 25^{th} 75^{th} percentile for indicators that demonstrated a distribution other than normal. The comparison of the two groups based on a quantitative indicator with a normal distribution, assuming equal variances, was conducted using Student's t-test. In cases where variances were unequal, Welch's t-test was employed. For the comparison of the groups using a quantitative

parameter whose distribution deviated from the normal one, the Mann–Whitney U-test was applied. Statistical significance was established at $p < 0.05$, indicating differences in the indicators [29].

Results and Discussion

The study revealed that almost all patients included in the study had a decrease in body weight as a result of the course of complex treatment. This is in line with results observed in parallel studies [30-33]. The comparative characteristics of the parameters of anthropometry in dynamics between groups are presented in **Table 4**.

Table 4. Dynamics of anthropometry parameters in patients under the influence of diet therapy

Index		Experimental group Me [25th ; 75th percentile]	Control group Me [25th ; 75th percentile]
Body weight, kg	Before diet	107.5 [103.9; 110.7]	102.5 [103.6; 115.4]
	After diet	103.2 [96.0; 106.6]	100.7 [94.4; 105.9]
	p-value	p≤0.05	p≤0.05
Body mass index, kg/m^2	Before diet	38.7 [36.7; 40.1]	38.3 [35.4; 39.2]
	After diet	37.5 [35.2; 39.1]	37.4 [33.5;38.6]

Despite the higher calorie content of the diet with CTE inclusion, in both groups, there was a comparable statistically different decrease in body weight from the initial one. The same results were obtained in recent relevant works [34-37]. The results of laboratory data before and after the course of diet therapy are presented in **Table 5**.

Table 5. Indicators of the clinical effectiveness of dietary therapy using CTE

Index		Experimental group M±SD	Control group M±SD
TG, mmol/L (0–1.7)	Before diet	1.3±0.55	1.5±0.31
	After diet	1.0±0.54	1.15±0.65
	p-value	p>0.05	p>0.05
HDLC, mmol/L (0.92–2.06)	Before diet	1.3±0.44	1.0±0.17
	After diet	1.2±0.36	1.0±0.15
	p-value	p>0.05	p>0.05
LDLC, mmol/L (0–3.8)	Before diet	4.1±0.83	3.7±0.98
	After diet	2.5±0.80	3.3±0.58
	p-value	p≤0.05	p>0.05

Against the background of diet therapy without changing drug therapy, a decrease in LDLC levels was noted in the experimental group compared with the control group while maintaining HDLC levels. There was no significant decrease in TG levels in the groups. At the same time, when adding CTE to the diet, there was no increase in the level of urea, creatinine, aspartate transaminase (AST), or alanine transaminase (ALT) **(Table 6)**.

Table 6. Indicators of biochemical blood analysis of patients of the experimental group

Index		M±SD
Urea, mmol/L (2.6–7.2)	Before diet	5.2±1.09
	After diet	4.9±1.11
	p-value	p>0.05
Creatinine, µmol/l (44.0–97.0)	Before diet	78.6±12.39
	After diet	82.4±15.43
	p-value	p>0.05
AST, Units/L (0-40.0)	Before diet	24.4 ±7.33
	After diet	24.3±7.39
	p-value	p>0.05
ALT, Units/L (0-40.0)	Before diet	25.0±10.82
	After diet	23.75±9.65
	p-value	p>0.05

These results indicate the safety of the proposed diet therapy and its effectiveness in reducing LDLC levels. However, it is worth noting that the study involved a small number of patients, which limits the generalizability of the results. Further research with larger sample sizes is needed to confirm these findings and determine the optimal duration and frequency of CTE use in diet therapy.

In conclusion, the addition of CTE to diet therapy without changing drug therapy showed promising results in terms of reducing LDLC levels while maintaining HDLC and TG levels. This suggests that CTE may be a useful tool in managing lipid metabolism and cardiovascular health [38-42]. However, further research is required to fully understand the potential benefits and limitations of this approach.

Conclusion

The comprehensive data on the assessment of the effect of CTE in the system of complex treatment of patients with dyslipidemia revealed several clinical benefits. The study showed that the course of diet therapy with CTE was well-tolerated by patients. Moreover, the results demonstrated a reduction in MT and BMI comparable to standard diet therapy. This suggests that CTE can be an effective tool for weight management in addition to its lipid-lowering properties. Furthermore, there was a positive impact on blood lipid profile. There was a statistically significant decrease in LDLC levels, while HDLC remained unchanged. This indicates that CTE may target specific cholesterol levels without affecting overall cardiovascular health. Additionally,

liver function markers such as AST, ALT, creatinine, and uric acid did not change among patients receiving CTE. This is important because it shows that CTE does not cause any adverse effects on liver function.

ACKNOWLEDGMENTS: None
CONFLICT OF INTEREST: None
FINANCIAL SUPPORT: None
ETHICS STATEMENT: The administration of medicines was carried out in accordance with clinical recommendations for diseases of a therapeutic profile. All patients were told about the composition, method of application and expected therapeutic and preventive effect of the applied diets, and a voluntary consent was signed to participate in the study.

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