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Original Article

Assessment of Serum Triglyceride and Cholesterol Levels in Sudanese Epileptic Patients Receiving Antiepileptic Drugs

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A B S T R A C T
Antiepileptic drugs such as Phenytoin (PHE), Valproic acid (VPA), and carbamazepine (CBZ) are disrupting Triglyceride and Cholesterol levels. Our study aimed to assess the level of serum Triglyceride and Cholesterol among Sudanese patients using antiepileptic drugs for more than one year at Khartoum State, Sudan. This analytical case control study was conducted from November 2019 to May 2020 in the National Center for Neurological Diseases and Sciences- Omdurman Teaching Hospital, Bahri Teaching Hospital, and Academic Educational Hospital at Khartoum State, Sudan. A total of 64 patients were enrolled in this study, 32 out of them were diagnosed as epileptic patients on antiepileptic drugs for more than one year (case group), and the other 32 patients (control group) were diagnosed with epilepsy but did not use antiepileptic drugs. Analysis of serum Triglyceride and Cholesterol was done by a fully automated machine (Mindray BS 240 clinical chemistry analyzer). The study showed that, the patients used Carbamazepine, Valproate and Phenytoin drugs, showed a significant decrease in mean serum concentration. of Triglyceride (86.1±38.8) when compare of main of control group (127.6±60.2) with *p- value* (0.002), and were significant increase in mean serum concentrations of Cholesterol (158.5±54.7) when compared of main of control group (150.5±75.2) with *p-value* (0.044) from data suggest that antiepileptic drugs affect serum Triglycerides and Cholesterol level. There was an increase in the mean of Triglyceride among patients who used Carbamazepine when compared to Valproic Acid and Phenytoin, and there was a decrease in the mean of Cholesterol among patients who used Phenytoin when compared to Valproic Acid and Carbamazepine therapy. From the present study, we concluded that serum Triglycerides and Total Cholesterol levels should be regularly monitored in patients using antiepileptic drugs for more than one year.

Introduction

Epilepsy was defined conceptually in 2005 as a disorder of the brain characterized by an enduring predisposition to generate epileptic seizures. This definition is usually practically applied as having two unprovoked seizures >24 h apart [1]. Epilepsy is considered a common chronic neurological disease. It is a serious health and social problem. It is estimated that 65 million people globally suffer from epilepsy, with 80% of these living in developing countries. Epilepsy is also a common neurological disease affecting all ages. Epilepsy affects more than 3 million people in the U.S. and about 50 million people worldwide [2,3,4]. The International League Against Epilepsy (ILAE) and the International Bureau for Epilepsy (IBE) have come to consensus definitions for the term's epileptic seizure and epilepsy. An epileptic seizure is a transient occurrence of signs and symptoms due to abnormal, excessive, or synchronous neuronal activity in the brain [3], a type of epilepsy including focal epilepsy, generalized epilepsy, and combined generalized and unknown epilepsy [5].

Serum concentration of lipids and lipoproteins in young adults is an important risk factor for the development of coronary heart disease in later life. Considerable data have suggested that, besides total cholesterol (TC), elevated triglyceride (TG) concentrations, increased LDL, and decreased HDL contribute to cardiovascular diseases. Thus, assessing changes in serum lipid levels following antiepileptic drugs may be useful to choose the safest drug and prevent cardiovascular complications in later life [6]. Antiepileptic drugs enhance hepatic P450 cytochrome (CYP450) system activity, leading to increased cholesterol synthesis or enzyme inhibitors, which exert the opposite action [7]. This study aims to assess the level of serum Triglyceride and Cholesterol among Sudanese patients using Antiepileptic Drugs for more than one year in Khartoum State, Sudan.

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Materials and Methods

Study design

It was an analytical case-control study.

Study area

The study was conducted in the Bahri Teaching Hospital, National Center for Neurological Diseases and Sciences, Academic Educational Hospital, and Omdurman Teaching Hospital at Khartoum State, Sudan.

Study period

The Study starts in November 2019 and runs through May 2020.

Study population

The thirty-two adult males and females who had epilepsy and were using antiepileptic drugs for at least one year, and (32) adult males and females also attended the hospital, had epilepsy, and had not received antiepileptic drugs.

Inclusion criteria

Adult males and females were diagnosed as epileptic patients based on EEG and the use of antiepileptic drugs for more than one year. Epileptic patients who received one of the following antiepileptic drugs (sodium valproate**,** phenytoin, or carbamazepine) for at least one year and who agreed to participate in the study were selected**.**

Exclusion criteria

Patients who were diagnosed with chronic disease (Diabetes, Hepatitis, and Cardiovascular disease), and any non-Sudanese patient were excluded.

Sample size

The sample size was calculated according to the known formula, which is used to reach a certain desired margin of error in the results. Sample size in this study was calculated for each category (on average) to give a maximum of error (0.05) with probability of (a=0.05) as follows: $N=z2\times p\times q\%d^2$. $N=3.3124\times0.025\times0.975\%$ 0.0025 = 32.2. Z-value in the normal curve corresponding to a level of confidence 95%=1.96. P=probability prevalence in the community (highest prevalence reported in Khartoum, 2.5%) or 0.025. Q = (1-p) =1-0.025. D = margin of error = 0,05.

Data collection

Data collected by the researcher during the rest-time of the patient. The collection sample was obtained by using a questionnaire in standard conditions, using gloves, a mask, and a new syringe. If there are any emergency cases, the physician has been called to see them and explain the study procedures and measurements to the volunteers. The blood samples were collected in a plain container, 5 ml from each patient was separated into serum by centrifugation technique (1200 rpm for 5 minutes). Serum was frozen at -20°C and stored in the research laboratory in Al-Neelain University till sample collection was completed. Samples for Triglyceride and Cholesterol were analyzed in the National Central Laboratory at Khartoum State.

Statistical analysis

Data analyzed using Statistical Packages for Social Sciences (SPSS -Version 25.0), t-test used to compare mean values of Triglyceride and Cholesterol level, *P value* was considered significant if (< 0.05) and Confidence Interval (CI 95%).

Ethical consideration

Ethical approval of the study was obtained from the Ministry of Health, Khartoum state, and Al-Neelain University, Faculty of Medical Laboratory Sciences. Written informed consent was also taken from the hospital and all participants before collecting the data and blood samples. Research purpose and objectives were explained to participants in clear, simple words. Participants were briefed about the objectives of the research, participation was entirely voluntary, and information was used anonymously.

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Results

In Table 1, the comparison between cases and controls shows that the mean age is slightly higher in the case group, but the difference is not statistically significant, suggesting that age is relatively balanced and unlikely to influence other outcomes. However, the BMI values reveal a significant disparity, with cases having a notably lower mean BMI than controls. This result, supported by a P-value of 0.000, indicates a meaningful difference in body composition that may warrant further discussion regarding its role in the study's context.

Table 1. Mean of Age and Body Mass Index (BMI) in cases and control groups.

Variables	Cases (Mean ± SD) n=32	Control (Mean ± SD) n=32	*P-value*
Age	34.0±11.8	29.7±9.61	0.116
BMI	22.0±4.84	27.1±4.37	0.000

Table 2 presents the mean values of triglycerides and cholesterol between the two groups. Triglyceride levels are significantly lower in the case group, suggesting a potential metabolic distinction that could be relevant to the research hypothesis. Cholesterol levels, while slightly higher in the case group, also show statistical significance, though the clinical relevance of this modest difference should be interpreted with caution. These findings may reflect underlying physiological or lifestyle factors that differentiate the groups.

Table 2. Mean comparison of study parameters in case versus control groups.

Parameters	Case (Mean ± SD)	Control (Mean ± SD)	*P-value*
Triglyceride	86.1±38.8	127.6±60.2	0.002
Cholesterol	158.5±54.7	150.5±75.2	0.044

In Table 3, the comparison across drug types—CBZ, VPA, and PHE—shows no statistically significant differences in triglyceride or cholesterol levels. The P-values indicate that lipid profiles do not vary meaningfully with the type of drug used in this sample. However, the small sample size in the PHE group may limit the statistical power of these comparisons, and this limitation should be acknowledged when interpreting the results. Overall, the data suggest that while group-level differences are evident, drug-specific effects on lipid parameters remain inconclusive within the current sample.

Table 3. Mean comparison of study parameters across the type of drug used.

Parameters	Mean ± SD			*P-value*
	CBZ n=18	VPA n=10	PHE n=4	
Triglyceride	90.5±45.2	83.8±32.7	72.0±18.6	0.686
Cholesterol	157.6±60.5	165.5±55.1	144.8±55.2	0.820

Discussion

The present study was designed to investigate the effect of antiepileptic drugs on lipid profile parameters, such as total cholesterol and triglyceride, when compared to the control group**.** A total of 64 patients were enrolled in this study. The patients were divided into two groups; the first group included 32 patients diagnosed as epileptic and using antiepileptic drugs for at least one year, and the second group was the control group, which included 32 patients diagnosed with epilepsy but not using antiepileptic drugs. This study revealed a significant increase in the mean total cholesterol level. This is attributed to a prolonged use of antiepileptic drugs as (CBZ, VPA and PHE) and may lead to adverse effects on lipid profile, particularly in serum cholesterol level. This is similar to the findings obtained by (Junejo GM, Channa NA, Khichi K, Shaikh M, Noorani L) [8]. However, we observed no statistically significant difference in the mean of triglyceride and total cholesterol level between drug groups, p value (0.686), (0.820) respectively.
This may be due to a variant type of drug related to epilepsy. Our study showed that not statistically significant changes in triglyceride levels after receiving Valproate drugs, these findings are agreed with the results obtained by (Salehiomran MR, Hosseini SE) [9].
Anti-Epileptic Drugs (AEDs) can cause hyperlipidemia by inducing the p450 enzyme system in the liver, which is involved in the synthesis and metabolism of cholesterol, in particular; CYP51A1 plays a key role in cholesterol synthesis. Also, carbamazepine stimulates the hepatic synthesis of cholesterols and increase

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the formation and pool size of bile acids, which in turn raises the level of intestinal absorption of cholesterol by facilitating micelle formation [9], which is a major risk factor for atherosclerosis and cardiovascular disease [10].

Our results after receiving an antiepileptic drug showed a significant decrease in the mean of triglyceride level, which was in line with the findings revealed by (Nadkarni J et al.) [11]. In this context, reports of some studies revealed that the use of antiepileptic drugs like phenytoin and carbamazepine increases lipid profile levels [12]. Based on cardiovascular epidemiological literature of Epilepsy disease, however, an increased serum cholesterol level may be regarded as an adverse effect on long-term antiepileptic therapy, which will increase the risk of coronary heart disease and sudden unexpected death (SUDEP) in epileptic patients. We recommend that more studies among epileptic patients and the effects of the antiepileptic drugs on other parameters as Low Density Lipoproteins (LDL-C) in large patients, should be done. Although small sample size and the lack of long-term follow-up of patients on antiepileptic drugs were the main limitations of our study, and results suggested a need for monitoring serum cholesterol and TG levels in patients receiving antiepileptic drugs.

Conclusion

From the present study, data suggested that antiepileptic drugs like Carbamazepine, valproate, and phenytoin affect serum triglycerides and cholesterol levels. Therefore, the serum cholesterol level should be regularly monitored in patients undergoing therapy with inducer anti-epileptic medicines.

Conflict of interest

The authors declare no conflicts of interest.

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