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Original Research Article

Cross sectional descriptive study to study the prevalence of metabolic syndrome among patients with epilepsy on antiepileptic drugs in a tertiary care centre

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ABSTRACT

Introduction: Epilepsy is the commonest neurological condition affecting people of all ages, race and social class. Patients with epilepsy have two to three times higher risk of mortality compared to general population. The role of epilepsy as a potential risk factor for metabolic syndrome and coronary artery disease is of interest.

Aims & Objectives: To study the prevalence of metabolic syndrome among patients with epilepsy.

Materials and Methods: This is a hospital based cross-sectional descriptive study. The subjects were selected from patients attending the epilepsy outpatient clinic of a single tertiary centre (GMCH, Udaipur) during the period of 15 months from January 2021 to March 2022. Fasting blood samples were drawn from them to estimate fasting blood glucose and fasting lipid profile.

Results: Males constituted two thirds of the subjects. Average age was 32.5 years. Mean duration of treatment was 13.6 years (range 3–48 years). 51.9% were on monotherapy. Valproate was used in 33 of the 45 (73.33%) patients. In localization related epilepsy, the commonest drug was carbamazepine used in 57.48%. Eight of the enrolled patients had diabetes mellitus and 35 had impaired fasting glucose. Systemic hypertension was detected in 11.5% patients. No significant association was noted between drug use and cardiovascular risk factors – diabetes mellitus, hypertension or dyslipidemia. Very significant association was noted on lipid profile for carbamzepine, phenytoin and clobazam.

Conclusions: Antiepileptic medications, especially valproate and carbamazepine have significant effects on the lipid profile and abdominal obesity in patients on treatment. Metabolic syndrome is more prevalent among adult patients <50 years of age with epilepsy compared to the general population in the same age group. This difference could be related to the effect of the antiepileptic medications, especially valproate. There is a need to monitor patients on antiepileptic medications regularly for development of dyslipidemia and obesity.

1. Introduction

Epilepsy is the most common neurological disorder, affecting people of all ages, races, and socioeconomic backgrounds. Epilepsy patients have a two to three times higher mortality rate than the general population.[1] In addition to deaths directly related to epilepsy, such as sudden death, trauma, status epilepticus, and aspiration pneumonia, as well as deaths related to the underlying causes of the seizures, increased mortality has been reported from seemingly unrelated causes such as heart disease and non-cerebral neoplasias.[2]

The Stockholm Heart Epidemiology Program studied a large cohort of patients with a history of acute

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myocardial infarction, and epilepsy was discovered to have a higher incidence of acute myocardial infarction than the general population, with an Odds ratio of 4.92.[3] Patients with a history of epilepsy hospitalisation had a worse prognosis when it came to myocardial infarction, according to the researchers. They have proposed a number of explanations for their findings, including the presence of a common underlying pathology for both, such as silent cerebrovascular disease, as well as the presence of common risk factors, such as smoking and alcohol abuse. A negative metabolic profile caused by some commonly used antiepileptic drugs, as well as direct seizure-related myocardial ischemia, were also considered as possible explanations. There are also conflicting reports claiming that epilepsy patients have a lower cardiovascular risk because antiepileptic drugs like carbamazepine raise HDL cholesterol levels in the blood.

The mortality and morbidity due to sudden cardiac death, myocardial infarction, and angina pectoris were found to be significantly higher in epilepsy patients, especially in symptomatic epilepsy and patients younger than 65 years old, in another study by Anneger's et al.[4]

Although some studies have looked into epilepsy mortality due to coronary artery disease, there are few that have looked into epilepsy as a potential risk factor for metabolic syndrome and coronary artery disease. There were no Indian studies on the link between epilepsy and vascular risk factors that could be found. Despite the fact that numerous previous studies have documented the higher risk, susceptibility of the Indian population to metabolic syndrome and coronary artery disease.[5]

This study was designed to look into the prevalence of metabolic syndrome in epilepsy patients who are on regular treatment in our population, with a focus on the role of epilepsy medications in the relationship. The findings will aid in the planning of future prospective studies in this field, as well as in the clinical setting for patient monitoring and management.

2. Aims & Objectives

To investigate the prevalence of metabolic syndrome in epilepsy patients.

3. Materials and Methods

This is a cross-sectional descriptive study conducted in a hospital. The participants were chosen from patients who attended an epilepsy outpatient clinic at a single tertiary centre (GMCH, Udaipur) for 15 months between January 2021 and March 2022.

Patients who attended the Epilepsy Clinic on a weekly basis were screened for study eligibility. The procedure was explained to those willing to give informed consent and meet the inclusion and exclusion criteria, and they were recruited into the study. The participants were interviewed using a detailed questionnaire to collect demographic information, epilepsy characteristics, and metabolic risk factors. They were given fasting blood samples to determine their fasting blood glucose and lipid profile.

3.1. Ethical considerations

The Institute Ethical Committee approved the study. All subjects who took part in the study gave their written informed consent. The informed consent process was carried out in accordance with the Declaration of Helsinki and the ICH E6 Guideline for Good Clinical Practice.

3.2. Inclusion criteria

1. Patients with epilepsy aged 20 to 49 years who consent to participate in the study.
2. Patients who have been taking antiepileptic drugs for at least three years.

3.3. Criteria for exclusion

1. Patients with diabetes mellitus, systemic hypertension, dyslipidemia, or other co-morbidities that alter the metabolic profile significantly before the onset of epilepsy.
2. Women who are pregnant or are 6 months postpartum.
3. Patients taking medications that alter the metabolic profile, such as steroids or oral contraceptives.

The Adult Treatment Panel III defines metabolic syndrome (National Institutes of Health, 2004)[6,7] The study used 5 metabolic syndrome criteria that were modified for the Asian Indian population.[8,9]

The presence of three of the five symptoms of metabolic syndrome was defined as

1. Central obesity (defined as a waist circumference of less than 90 cm for men and 80 cm for women).
2. High triglyceride levels (>150 mg/dL or special treatment).
3. Low HDL cholesterol (40 mg/dL in men, 50 mg/dL in women, or a specific treatment for this).
4. Hypertension (systolic blood pressure > 130 or diastolic blood pressure > 85 mm Hg or treatment of previously diagnosed hypertension).
5. High fasting plasma glucose (FPG > 110 mg/dL or type 2 diabetes previously diagnosed).

The Students t-test was used to compare the means of numeric variables between groups. The Chi-square test or Fisher's Exact test were used to compare proportions. For statistical significance, P values of less than 0.05 were used. The statistical analysis was carried out using the SPSS v.20 software.

4. Results

A total of 183 patients who met the study's inclusion and exclusion criteria were chosen at random. There were 120 males and 63 females among the subjects, representing 65.93 percent and 34.07 percent, respectively. Two-thirds of the participants were men.

Adults between the ages of 20 and 49 were chosen to represent those with the lowest age-related risk of coronary artery disease and metabolic syndrome. Almost half of them (44.26 percent) were between the ages of 20 and 29. Patients aged 30–39 years old made up 27.32 percent of the total, while those aged 40–49 years old made up 28.42 percent. The subjects were 32.5 years old on average.

4.1. Duration of therapy

Treatment lasted an average of 13.6 years (range 3–48 years). Within one year of onset, 129 patients (70.5%) began treatment. Only ten years after the onset of seizures, 5.5 percent of patients began regular antiepileptic treatment.

4.2. Monotherapy versus polytherapy

Monotherapy was used by 95 patients (51.9%). Valproate was the most commonly used monotherapy medication, accounting for 40% of cases. Carbamazepine (26.32 percent) and phenytoin (17.9%) were also used as single drugs to control epilepsy in a significant number of patients.Table 1

Table 1: Distribution of patients based on monotherapy drug

Drag	Number of patients	% of monotherapy	% of total
Valproate	38	40.0%	20.8%
Carbamazepine	25	26.3%	13.7%
Phenytoin	17	17.9%	9.3%
Others	15	15.8%	8.2%

68 patients received dual therapy (37.16 percent). The most common combination was carbamazepine and clobazam, which was used in 36 (19.6%) of the patients. Polytherapy was used by 20 patients (10.9 percent) who were taking three or more medications.

4.3. Type of epilepsy and specific drug

Valproate was the most commonly used drug in patients with primary generalised epilepsy. Valproate was used in 33 of the 45 patients (73.33%). Carbamazepine was the most commonly used drug in patients with localization-related epilepsy, accounting for 57.48 percent (73 of 127 patients). Phenytoin was the second most commonly used drug for partial seizures, being used in 34 patients (26.77 percent).

5. Risk Factors for Cardiovascular Disease

5.1. Metabolic risk factors

At the time of enrollment, five of the patients were receiving diabetes treatment. In three patients, blood sugar analysis revealed abnormal fasting glucose, indicating diabetes mellitus. Eight of the enrolled patients had diabetes, and 35 had impaired fasting glucose levels. Fasting blood sugar levels ranged from 60 to 202 mg/dL, with an average of 92.78 (16.4) mg/dL.

In 21 patients, systemic hypertension was discovered (11.5 percent). Eleven patients admitted to having dyslipidemia. A total of 50.8 percent (93) of the patients had abnormal fasting lipid levels or were receiving treatment for them. Total cholesterol levels were 213.57 49.9 mg/dL on average (range 121 – 405 mg/dL). Serum LDL, HDL, and triglycerides had average values of 143.78, 45.66, and 119.3 mg/dL, respectively.

Abdominal obesity, as measured by increased abdominal circumference, was found in 81 patients (44.3%), with 46 men (38.33%) and 35 women (55.55 percent). Males had an average abdominal circumference of 86.54 cm and females had an average abdominal circumference of 83.13 cm.

There was no significant link between the duration of epilepsy and the presence of metabolic syndrome.Table 2

There was no link between the length of treatment and the number of drugs used and the presence of metabolic syndrome.Table 3

5.2. Type of drugs and metabolic syndrome

Only five of the drugs – carbamazepine, phenytoin, valproate, clobazam, and phenobarbitone – had sufficient numbers to reliably assess significance.

A higher valproate dose was found to be linked to a higher risk of metabolic syndrome. The duration of valproate use, on the other hand, was not significant. There was no significant difference in blood sugar or blood pressure levels among valproate patients. The drug had a mixed effect on the lipid profile, lowering LDL cholesterol while increasing triglycerides and lowering HDL cholesterol. Patients taking valproate have a higher risk of abdominal obesity (52.1 percent vs 40.0 percent).Table 4

In the last five years, there was no significant link between metabolic syndrome and valproate use. However, in this study, the link between phenobarbitone use and metabolic syndrome was found to be significant.Table 5

There was no link found between drug use and cardiovascular risk factors such as diabetes, hypertension, or dyslipidemia.Table 6

Carbamazepine, phenytoin, and clobazam all showed a strong lipid profile association. The use of carbamazepine was linked to higher total cholesterol, LDL, and HDL levels. Valproate use has been linked to lower total cholesterol,

Table 2: Duration of epilepsy and metabolic syndrome

			Metabolic syndrome		
			Yes	**No**	**Total**
Type of epilepsy	<5yrs	No. of cases (%)	8(50.0%)	8(50.0%)	16(100.0%)
	5 - 9yrs	No. of cases (%)	16(32.7%)	33(67.3%)	49(100.0%)
	10 - 14yrs	No. of cases (%)	8(21.6%)	29(78.4%)	37(100.0%)
	15 - 19yrs	No. of cases (%)	5(20.0%)	20(80.0%)	25(100.0%)
	≥ 20yrs	No. of cases (%)	17(30.4%)	39(69.6%)	56(100.0%)
Total		Count (%)	54(29.5%)	129(70.5%)	183(100.0%)
P value – 0.225					

Table 3: Number of drugs and metabolic syndrome

			Metabolic syndrome		
			Yes	**No**	**Total**
Number of drugs	Monotherapy	No. of cases (%)	33(34.7%)	62(65.3%)	95(100.0%)
	Polytherapy	No. of cases (%)	6(30.0%)	14(70.0%)	20(100.0%)
	Dual therapy	No. of cases (%)	15(22.1%)	53(77.9%)	68(100.0%)
Total		Count (%)	54(29.5%)	129(70.5%)	183(100.0%)
P value – 0.216					

Table 4: Relationship between valproate dose and duration and metabolic syndrome

	Metabolic syndrome		
Valproate	**Present**	**Absent**	**P value**
Duration of intake (years)	2.88	1.95	0.25
Dose (mg)	386.11	177.52	0.01

Table 5: Drug use in the last five years and metabolic syndrome

	Metabolic syndrome		P value
	Present	**Absent**	
Carbamazepine	20 (25.3%)	59 (74.7%)	0.279
Phenobarbitone	4 (13.8%)	25 (86.2%)	<0.05
Phenytoin	18 (36.0%)	32 (64.0%)	0.238
Clobazam	17 (25.4%)	50 (74.6%)	0.351
Valproate	27 (34.6%)	51 (65.4%)	0.192

LDL cholesterol, and HDL cholesterol. Clobazam use was linked to higher HDL levels.Table 7

The current study is a prospective cross-sectional study to determine the prevalence of metabolic syndrome in a group of 183 epilepsy patients who were randomly selected from our institute's Epilepsy Clinic. A minimum of three years on antiepileptic medications was used as a mandatory inclusion criterion to ensure that the effect of antiepileptic medications was consistent. This is the study that looked at the metabolic profile of epilepsy patients.

6. Discussion

6.1. Demographic characteristics of the population

Males made up two-thirds of the participants in this study. Males have a higher prevalence of epilepsy than females, according to population-based studies in India, both in urban and rural areas. Men have a prevalence rate of 5.88 per 1000 people, while women[10] have a rate of 5.51. 7. The type of epilepsy explains the gender distribution: hormonal differences in the prevalence of certain epilepsy syndromes, increased occurrence of certain risk factors like head injury in males, and so on.

6.2. Type of epilepsy

Localization-related epilepsy accounted for roughly 70% of the cases in the current study, while primary generalised epilepsy accounted for only 25% of the cases. Another 6% of patients had only generalised seizures and were unable to be classified as primary or secondary based on clinical history, EEG, or imaging data. Patients with symptomatic generalised epilepsy are not included in this study because most of them have mental sub-normalities, making informed consent difficult. Sridharan et al[8] found a wide range of types of seizures in the general population,

Table 6: Drugs and vascular risk factors

Drug	Present	Absent	P value
Carbamazepine (n = 63)			
Diabetes	3 (4.7%)	61 (95.3%)	1.00
Hypertension	6 (9.4%)	58 (90.6%)	0.513
Dyslipidemia	31 (48.4%)	33 (51.6 50	0.636
Clobazam (n= 54)			
Diabetes	2 (3.7%)	57 (96.3%)	1.00
Hypertension	5 (9.3%)	49 (90.7%)	0.543
Dyslipidemia	23 (42.6%)	31 (57.4%)	0.150
Phenytoin (n = 48)			
Diabetes	4 (10.3%)	35 (89.7%)	0.065
Hypertension	5 (12.8%)	34 (87.2%)	0.779
Dyslipidemia	23 (59.0%)	16 (41.0%)	0.251
Valproate (n = 39)			
Diabetes	1 (2.1%)	47 (97.9%)	0.683
Hypertension	5 (10.4%)	43 (89.6%)	0.789
Dyslipidemia	28 (58.3%)	20 (41.7 5)	0.225
Phenobarbitone (n=23)			
Diabetes	2 (8.69%)	21 (91.31%)	1.00
Hypertension	1 (4.35%)	22 (95.65%)	0.543
Dyslipidemia	8 (34.8%)	15 (65.2%)	0.100

Table 7: Drugs and lipid profile

Drug	**Total cholesterol**	**LDL cholesterol**	**HDL cholesterol**	**Triglyceride**
Carbamazepine (n= 63)				
Yes	231.8	157.7	49.9	117.8
No	203.8	136.3	43.4	120.1
p value	<0.001	0.001	0.001	0.841
Clobazam (n= 54)				
Yes	221.9	148.1	49.6	118.7
No	210.7	142.0	44.0	119.5
p Value	0.143	0.377	0.006	0.948
Phenytoin (n=48)				
Yes	221.1	147.7	46.3	133.6
No	211.5	142.7	45.5	115.4
p value	1.291	0.516	0.747	0.177
Valproate (n= 39)				
Yes	192.8	127.1	40.0	127.4
No	220.9	149.7	47.7	116.4
p value	0.143	0.001	<0.006	0.379
Phenobarbitone (n= 23)				
Yes	213.45	142.13	44.76	124.76
No	213.60	144.03	45.84	118.27
p Value	0.988	0.843	0.679	0.608

with primary generalised seizures accounting for 45.45-86 percent of all reported seizures and partial seizures with or without generalisation accounting for 11.45-54.54 percent. Approximately 60% of western literature Localization-related epilepsy affects a large percentage of patients who visit tertiary centres. The low number of patients with generalised epilepsy in our cohort could be due to the fact that the cohort was drawn from a tertiary referral centre where more treatment-resistant cases were referred.

6.3. Therapy of epilepsy

The study population had a wide range of epilepsy treatment durations, ranging from 3 to 48 years. Monotherapy was given to 52 percent of the patients. Although carbamazepine was the most commonly used drug, valproate was the most commonly prescribed monotherapy. Other studies found a similar percentage of patients on monotherapy. In a cohort from an Eastern Indian tertiary centre, 54 percent of patients could be kept on monotherapy.[9]

In 2008, phenytoin (31 percent), levetiracetam (25 percent), and carbamazepine (8 percent) were the most commonly used monotherapies in adults in a study conducted by Wang et al[11] in the United States. The medication used depends on the type of epilepsy syndrome being treated, with valproate being preferred in primary generalised epilepsies and carbamazepine being used more frequently in localised epilepsies.

6.4. Effect of antiepileptic drugs on the metabolic profile

Many studies have shown that traditional anticonvulsant medications, particularly valproate, carbamazepine, and phenytoin, have significant metabolic effects. Anticonvulsants can affect liver function and make the hepatic microsomal enzyme system more active.[12,13] The altered metabolism of various substances such as drugs and lipids is linked to this enzyme induction phenomenon.

A significant increase in serum levels of triglyceride, total cholesterol, HDL, and VLDL cholesterol was observed in patients receiving combination therapy of either phenytoin and phenobarbitone or phenytoin and carbamazepine or phenytoin alone in a study conducted in Delhi[14] to establish the relationship between antiepileptic drug use and serum lipid levels. Patients who received carbamazepine alone had significant increases in serum triglyceride and VLDL cholesterol levels, but no significant changes in total cholesterol or HDL cholesterol levels.

Carbamazepine was linked to higher total and HDL cholesterol levels in our study, whereas valproate therapy significantly reduced both. Both had no discernible effect on triglyceride levels. Carbamazepine raised and valproate reduced LDL cholesterol levels to statistically significant levels, indicating that changes in HDL cholesterol profile alone are not responsible for changes in serum total cholesterol. The modifications could be due to the two drugs have different effects on microsomal enzymes. The enzymes are induced by carbamazepine and inhibited by valproate. Carbamazepine stimulates cholesterase synthesis in the liver and increases bile acid formation and pool size, which increases cholesterol absorption in the intestine by facilitating micelle formation.[15] Multiple studies have linked phenytoin to higher serum cholesterol levels. Although our patients showed the same trend, the difference was not statistically significant. To establish the same, a larger study with a greater number of patients taking each antiepileptic medication may be required.

Valproate therapy has been linked to an abnormal metabolic profile in the past. Valproate-treated patients had higher circulating insulin concentrations relative to body mass index, higher uric acid and triglyceride levels, and lower high-density lipoprotein cholesterol concentrations, according to Pylvalnen et al.[10] Many of valproate's metabolic side effects are likely related to the weight gain associated with its use. According to Verrotti et al,[14] up to 40% of patients on valproate therapy develop obesity. The BMI at the start of valproate therapy was not a predictor of obesity or metabolic syndrome development.[16,17]

7. Conclusions

The patient's gender or epilepsy characteristics had no effect on metabolic syndrome or vascular risk factors. Antiepileptic drugs, particularly valproate and carbamazepine, have a significant impact on lipid profiles and abdominal obesity in patients taking them. Metabolic syndrome is more common in adult epilepsy patients under the age of 50 than in the general population of the same age group. This disparity could be due to the antiepileptic medications' effects, particularly valproate. To figure out the exact mechanism, more large-scale research may be required. The study emphasises the importance of routinely monitoring antiepileptic medication patients for the development of dyslipidemia and obesity.

8. Limitations of the Study

1. Patients on all medications were considered for the study thereby resulting in a smaller number in subgroup analysis.
2. Almost half the patients were on more than one antiepileptic medication.
3. An internal control population was not selected.

9. Source of Funding

None.

10. Conflict of Interest

Author declare no conflict of interest.

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