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IMPACT OF COVID-19 TREATMENT AND PANDEMIC ON EPILEPTIC PATIENTS – A CROSS-SECTIONAL STUDY

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ABSTRACT: Background: The SARS-CoV-2 pandemic has severely impacted individuals with epilepsy, increasing their risk of seizure exacerbation and medication dependence. **Methods:** This cross-sectional study evaluated antiepileptic drug (AED) prescribing management and adverse drug reactions in patients at a tertiary care hospital from September 2020 to September 2022 influenced by COVID-19 Pandemic. **Results:** This study enrolled 1272 participants, comprising two groups: Group 1 (636 patients) with both epilepsy and COVID-19 (61.3% males, 38.7% females) and Group 2 (636 patients) with COVID-19 and no epilepsy history (63.4% males, 36.6% females). The COVID-19 pandemic exerted a profound impact on the mental well-being of epilepsy patients, manifesting as heightened anxiety (68.3%), depression (47.2%), and sleep disruptions (29.6%). These psychological issues were more prevalent in epilepsy patients compared to non-epilepsy patients. Most patients were 51-60 years old (17.92%) or 41-50 years old (16.50%). 59.2% had epilepsy for over five years. **Conclusion:** This research underscores the detrimental effects of antiepileptic drugs (AEDs) on epileptic patients' quality of life, necessitating tailored treatment approaches and enhanced patient care. The COVID-19 pandemic has exacerbated psychological distress among epilepsy patients. Our findings emphasize the importance of optimizing AED regimens, addressing mental health issues, and closely monitoring adverse drug reactions. This study provides valuable insights into the pandemic's impact on epilepsy patients, informing healthcare providers on strategies to enhance patient outcomes and develop more effective treatment protocols. This study contributes to understanding COVID-19's impact on epilepsy patients, guiding healthcare providers to improve patient outcomes and develop more effective treatment plans.

INTRODUCTION: The SARS COV-2 pandemic is associated with critical and potentially fatal outcomes mainly targeting the respiratory system. Typical symptoms which include fever, cough and fatigue with possible neurological complications [1-2]. This pandemic has severely strained healthcare systems particularly for those with epilepsy.

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Patients with epilepsy are at heightened risk of intensified seizures related health issues and reliance on daily medication making them exceptionally susceptible to healthcare disruptions [3].

Epilepsy is a neurological condition marked by recurring seizures, triggered by irregular brain electrical activity due to neuronal dysfunction or hyperexcitability. This can lead to involuntary movements and potential brain or physical harm. The World Health Organization (WHO) estimates that approximately 50 million people globally live with epilepsy, making it a prevalent neurological condition and significant public health issue,

disproportionately affecting children and older adults [3]. In India, epilepsy affects over 10 million individuals, with approximately 2 million experiencing forms of the condition that are resistant to treatment [4]. Epilepsy can be broadly categorized into three types: acquired, idiopathic, and genetic or developmental, with the latter often manifesting in childhood [5]. Additionally, epilepsy is frequently accompanied by cognitive and developmental impairments, which can complicate treatment and require close collaboration between healthcare providers and parents, particularly in pediatric cases [6]. The International League against Epilepsy (ILAE) has established a framework that classifies epilepsy into six primary etiological groups: structural abnormalities, genetic predispositions, infectious origins, metabolic disorders, immune-related causes, and unknown factors [7]. Electroencephalography (EEG) and magnetic resonance imaging (MRI) are essential diagnostic tools that aid in the accurate diagnosis and ongoing management of epilepsy [8].

Annually, epilepsy is responsible for around 125,000 deaths globally, with low- and middle-income countries accounting for approximately 80% of these fatalities [9]. Additionally, individuals with epilepsy often experience comorbidities, which affect over 50% of this population. These comorbid conditions include various psychiatric disorders, such as depression, anxiety, and psychosis, as well as physical health issues like diabetes, arthritis, and chronic obstructive pulmonary disease (COPD) [10].

Genetic factors can contribute to the development of these comorbidities, with people with epilepsy being up to eight times more likely to experience them compared to the general population. Other common comorbidities include cognitive decline, migraines, cardiovascular conditions, and autoimmune disorders like systemic lupus erythematosus (SLE) and type 1 diabetes mellitus [10]. Effective epilepsy management involves routine comorbidity screening to optimize antiepileptic drug (AED) efficacy and tolerability [11]. Immunosuppressants may possess antiseizure properties but can interact with antiepileptic drugs (AEDs) [11]. The first aim of epilepsy treatment is to gain complete seizure control with minimal side effects, a goal that is currently possible in about 50% of patients using available AEDs. The selection of AEDs is influenced by factors such as type of epilepsy, age and gender, comorbidities, drug interactions, and treatment cost. Epileptic women require special attention due to the risks of teratogenicity, weight changes, and hormonal fluctuations [12]. Mental health conditions, notably depression and anxiety, significantly influence seizure management and overall well-being. Certain antiepileptic drugs (AEDs) like carbamazepine & phenobarbital can induce cytochrome P450 enzymes, potentially decreasing the effectiveness of concurrent medications. including anticoagulants and antibiotics. While around 70% of patients achieve good seizure control with AEDs, 20% to 30% continue to experience seizures that are resistant to treatment [13]. Drug interactions, especially with antibiotics used in emergency situations, can complicate epilepsy management [14].

Adverse drug reactions (ADRs) not only impair the patient's quality of life but also increase healthcare expenses [15]. Consequently, monotherapy is generally preferred over polytherapy, and therapeutic drug monitoring (TDM) is recommended for specific AEDs to optimize dosing and reduce the likelihood of adverse effects [16]. During the COVID-19 pandemic, individuals with chronic illnesses faced significant challenges, making them more susceptible to adverse outcomes beyond the immediate risk of infection.

Although people with epilepsy were not generally considered at higher risk of contracting COVID-19 or experiencing severe complications from it, the pandemic's indirect effects could still harm their health and well-being. Factors such as financial strain, increased anxiety, social isolation, decreased physical activity, and disruptions to education, employment, and family life may have heightened their risk of seizures [17]. Gaps in healthcare access and management increase seizure risk, worsening symptoms and potentially leading to comorbidities like depression, anxiety, and premature mortality [17].

Study Objectives: The aim of the study was to determine the effect of COVID-19 treatment and pandemic on epileptic patients and non-epileptic patients measuring such as the age, gender, other

demographic details, psychological risk factors, prescribing patterns of AED, Drug -Drug interactions with the drugs prescribed for COVID-19 vs AED and ADR of AEDs in epileptic patients presenting to a tertiary care hospital.

MATERIALS AND METHODS: This cross-sectional study evaluates the safety and efficacy of anti-epileptic medications while exploring the impact of COVID-19 on patients with and without epilepsy, admitted between September 2020 and September 2022.

The main goal of this study is to examine the prescribing trends, adverse drug reactions (ADRs), and related factors of antiepileptic medications. The study population consists of COVID-19 patients with and without epilepsy, who were assessed at baseline and monitored for adverse events throughout the study period. This study received ethical clearance from the Mallige Hospital Institutional Review Board (MCP/RRB/011/22-23).

Data for this study was gathered from the medical records department using a standardized data collection form. Subsequently, the distribution and administration of antiepileptic medications among patients were examined through a review of their medication charts.

This study screened 636 patients undergoing COVID-19 treatment, applying inclusion criteria and excluding pregnant women. Eligible participants underwent comprehensive assessments, including:

1. Demographic information.
2. Epilepsy characteristics (type, etiology).
3. Antiepileptic drug (AED) treatment regimens.
4. COVID-19 treatment-related drug-drug interactions (DDIs).
5. Psychological factors (depression, anxiety, sleep disturbances) related to the pandemic.

Adverse drug reactions (ADRs) were evaluated using the Naranjo Scale during clinic visits and reported by parents or attenders to physicians during hospitalization. Drug-drug interactions were assessed using online databases Micromedex and Lexicomp, with all identified ADRs and DDIs documented accordingly.

This study employed the Depression, Anxiety, and Stress Scale (DASS-21) to evaluate psychological factors, with scoring criteria derived from prior research [23]. The DASS-21 subscales were classified as follows:

Depression Severity:

Normal: 0–9

Mild: 10–12

Moderate: 13–20

Severe: 21–27

Extremely severe: 28–42

Anxiety Levels:

Normal: 0–6

Mild: 7–9

Moderate: 10–14

Severe: 15–19

Extremely severe: 20–42

Stress Intensity:

Normal: 0–10

Mild: 11–18

Moderate: 19–26

Severe: 27–34

Extremely severe: 35–42

Additionally, the Pittsburgh Sleep Quality Index (PSQI) was utilized to assess sleep quality. It consisted of 19 self-reported items grouped into seven domains:

- Sleep duration
- Sleep disturbances
- Sleep latency

- ❖ Daytime dysfunction
- ❖ Sleep efficiency
- ❖ Overall sleep quality
- ❖ Use of sleep medications

Each component was rated on a scale from 0 to 3, with higher scores representing increased levels of dysfunction. The total score ranged from 0 to 21, with higher scores reflecting poorer sleep quality.

Study Setting and Population: The study, carried out at Mallige Hospital in Bangalore, India, involved 1272 participants across all age groups, divided into two groups: Group 1 (636 participants with both epilepsy and COVID-19) and Group 2 (636 participants with COVID-19 but no epilepsy). Treatment was discontinued in two individuals from the first group due to phenytoin toxicity.

Data Analysis: Data analysis utilized SPSS Software (Version 27), presenting qualitative data as frequencies and quantitative data as mean ± SD, while Pearson correlation coefficient determined association strengths.

Criteria: From 1272 potential participants aged 18 and above, two groups were formed after applying inclusion and exclusion criteria:

Group 1: Individuals diagnosed with both epilepsy and COVID-19

Group 2: Individuals diagnosed with COVID-19 but without epilepsy

RESULTS:

Demographics of Patients with Epilepsy (PWE): This study enrolled adults aged 18 and older, categorized into 10-year age groups, with a mean age of 56.5 years. Among 636 patients with epilepsy, majority of patients (17.92%) fell within the 51-60 age group, followed by 41-50 (16.50%), with a male-to-female ratio of 61.3% to 38.7%. , while Group 2 peaked at 61-70 (19.9%) and 31-40 (19.3%) years. The link between epilepsy and age may be attributed to the higher prevalence of neurological conditions with epileptogenic potential, such as stroke and dementia, in older individuals. Factors like etiology and lifestyle significantly influence epilepsy outcomes.

A p-value of <0.001 indicates a highly significant statistical relationship. Thus, the likelihood of developing epilepsy tends to rise with advancing age. Additionally, the Pearson correlation coefficient of 0.244 demonstrates a positive linear relationship between age and epilepsy, suggesting a moderate increase in epilepsy risk as age progresses **Table 1.**

TABLE 1: DEMOGRAPHIC DETAILS RELATED TO THE PATIENTS

Variables	Mean of Group-1 (%)	Mean of Group-2 (%)
Mean age	±56.5 years	±53.5years
Range in years	18-95	18-89
Age groups		
18-30	102(16.0)	96(15.1)
31-40	99(15.5)	123(19.3)
41-50	105(16.5)	109(17.1)
51-60	114(17.9)	86(13.5)
61-70	78(12.2)	127(19.9)
71-80	63(9.9)	56(8.8)
81-90	57(8.9)	31(4.9)
91-100	18(2.8)	8(1.2)
Gender		
Male	390(61.3)	403(63.4)
Female	246(38.7)	233(36.6)
Comorbidity		
Yes	529(83.2)	487(76.6)
No	107(16.8)	149(23.4)
Surgical history		
Yes	396(62.3)	347(54.5)
No	240(37.7)	289(45.4)
Alcohol intake		
No	274(43.1)	282(44.3)
Yes	362(56.9)	354(55.7)
Smoking		
Yes	259(40.7)	263(41.4)
No	377(59.3)	373(58.6)
Tobacco		
Yes	103(16.2)	89(14.0)
No	533(83.8)	547(86.0)
Education		
Basic education	442(69.5)	428(67.3)
Graduated	194(30.5)	208(32.7)

Group 1; COVID patients with epilepsy, Group 2; COVID_19 patients

A significant correlation between epilepsy and gender was found (p = 0.039), with males exhibiting higher epilepsy prevalence. Additionally, males had higher rates of comorbid conditions such as cerebrovascular accidents, hypertension, and diabetes, indicating complex sex-specific factors contributing to epilepsy risk.

Epilepsy: Our study revealed that 59.2% (377/636) of patients had epilepsy for over five years, with 45.4% experiencing generalized epilepsy. Notably, 21.8% (139/636) reported seizure worsening during lockdown. Monotherapy was prevalent (50.4%), with Levetiracetam (37.38%) and Pregabalin (16.82%) being common choices **Table 2.**

TABLE 2: DETAILS RELATED TO THE PATIENTS EPILEPSY CONDITION

Disease duration	
< 1 year	75(11.7)
1 - 5 years	184(28.9)
> 5 years	377(59.2)
Seizure type	
Generalized	289(45.4)
Focal	272 (42.7)
Absence	49(7.7)
Myoclonus	26(4.0)
AED treatment type	
Monotherapy	321 (50.4)
Dual therapy	213(33.49)
Polytherapy	102(16.0)
Last seizure occured before admission	
Within last 3 months	268(42.1)
More than 3 months	378(59.4)
Worsening of seizure during pandemic	
Yes	139(21.8)
No	497(78.1)
Last medicine revised before the pandemic	
Within last 3 months	237(37.2)
Three months or earlier	399(62.7)
Missing to take medication	
Often	130(20.4)
Rarely	506(79.5)
Difficulty in the availability of medication during pandemic	
Yes	384(60.3)
No	252(39.6)
Change of seizures during infection	
Increase	84(13.2)
Reduced	66(10.3)
No change	486(76.4)

Impact of Covid-19 Pandemic on Psychological and Demographic Factor: An analysis of 1,272 participants revealed notable patterns in education and employment. A substantial proportion (68.3%) had a basic education, while 31.6% held advanced degrees. The COVID-19 pandemic led to job loss for 30.2% of participants, exacerbating psychological distress. Mental health assessments using the DASS21 scale showed that 426 and 320 Research participants in Group 1, and 288 and 241 in Group 2, experienced anxiety and depression. Furthermore, PSQI results indicated insomnia affected 188 participants in Group 1 and 134 in Group 2."

TABLE 3: PSYCHOLOGICAL FACTORS, AND SLEEP QUALITY DURING THE PANDEMIC

DASS 21—ANXIETY DURING THE PANDEMIC

Variables	Frequency of Group 1	Frequency of Group 2	p-value
No anxiety	210 (33.0)	348(54.7)	0.037*
Mild anxiety	178 (27.9)	131(20.5)	
Moderate anxiety	116 (18.2)	76(11.9)	
Severe anxiety	58 (9.1)	47(7.3)	
Extremely severe anxiety	74 (11.6)	34(5.3)	

DASS 21—DEPRESSION DURING THE PANDEMIC

Variables	Frequency of Group-1	Frequency of Group-2	p-value
No depression	316 (52.8)	395(62.1)	0.042*
Mild depression	122 (10.3)	109(17.1)	
Moderate depression	67 (12.7)	69(10.8)	
Severe depression	82 (15.0)	45(7.0)	
Extremely severe depression	49 (8.9)	18(2.8)	

PSQI—SLEEP DURING THE PANDEMIC

Variables	Frequency of Group 1	Frequency of Group 2	p value
Impaired sleep quality	188 (29.6)	134(21.1)	0.02*
Good sleep quality	448 (70.4)	502(78.9)	

The COVID-19 pandemic exerted a profound psychological toll on individuals with epilepsy, yielding significant correlations between pandemic exposure and heightened symptoms of depression ($p = 0.042$), anxiety ($p = 0.037$), and disrupted sleep patterns ($p = 0.021$).

Association of Adverse Drug Reaction Using Anti-Epileptic Drugs: Among 636 patients, 82 (12.9%) exhibited suspected adverse drug reactions (ADRs), primarily linked to valproate (19 cases, 23%). Phenytoin, carbamazepine, oxcarbazepine, and levetiracetam also showed significant associations. The Naranjo Scale categorized most ADRs as possible or probable. Treatment was discontinued in two phenytoin users due to gum hypertrophy toxicity."

TABLE 4: ASSOCIATION OF ADVERSE DRUG REACTION

Incidence of ADR	Number of patients (N)	P Value
Yes	164	0.018*
No	472	

The coefficient of 0.202 between drugs and ADR suggests a positive but relatively weak linear relationship ($p = 0.018$) indicates that this correlation is statistically significant at the 0.05 level.

The most common adverse events were dizziness and sedation followed by nausea.

TABLE 5: AED RELATED ADR

	VPA	PHT	LEV	CBZ	OCZ
Dizziness	+	+	+++	++	---
Headache	+++	---	---	++	---
Loss of appetite	---	+	---	---	---
Fatigue	++	++	---	---	---
Nausea	+++	---	++	+++	---
Sedation	---	++	+++	---	++
Gingivitis	---	++	---	---	

Association of Drug-Drug Interaction of Anti-Epileptic Drugs and Covid-19 Drugs: We identified prescriptions with multiple drugs and suspected drug-drug interactions (DDIs), analyzing them with a drug interaction checker to classify mechanisms. Notably, antiepileptic drugs (AEDs) interact with other medications through hepatic enzyme induction or inhibition, emphasizing DDI monitoring's importance. In 1,272 patients, common COVID-19 treatments included Azithromycin (43.8%), Chloroquine (26.9%), Hydroxychloroquine (24.5%), Remdesivir (23.7%), Lopinavir (17.2%), and Tocilizumab (4.8%).

"Theoretical analysis revealed 109 potential drug-drug interactions (DDIs) between antiepileptic drugs (AEDs) and COVID-19 treatments in patients with epilepsy (PwE). Notably, Carbamazepine-Chloroquine interactions reduced AED efficacy (13.0%), while Phenytoin-Tocilizumab interactions induced hepatic enzymes (7.8%). Lopinavir-Lamotrigine interactions necessitated dose adjustments (4.2%). In contrast, non-epilepsy patients showed decreased DDI risk, with common interactions involving anti-hypertensives and anti-diabetics. Statistical analysis revealed significant DDI correlations between AEDs and COVID-19 medications ($p = 0.031$)."

Common Prescribing Patterns of Anti-Epileptic Drugs in Covid-19 Patients: Research involving 636 patients identified Levetiracetam as the most frequently prescribed therapeutic agent, accounting for 41.98% (267 patients) of the study population. Its popularity can be attributed to its lower incidence of side effects and minimal interactions with COVID-19 medications, rendering it a preferred choice over alternative AEDs.

Incidence of Mortality Risk Rate of Covid-19 in PwE: Among 1,272 patients, mortality rates were 12.2% (78/636) in one group and 10.3% (66/636) in another, with comorbidities like diabetes, hypertension, cerebrovascular accidents, and advanced age. The difference in mortality between patients with epilepsy (PwE) and non-PwE was statistically insignificant ($p = 0.082$).

DISCUSSION: This research analyzed 636 prescriptions via a specially designed data collection instrument, with follow-up care provided at a tertiary care facility. Epilepsy, a common neurological disorder, imposes considerable morbidity and mortality burdens. Inadequate patient education and support may increase suffering and reduce quality of life (Arfman IJ *et al.,* 2020). Our study found that COVID-19 poses a higher risk for persons with epilepsy compared to those without it.

Higher prevalence is often observed in our sample in those over 55, but this study found that patients between the ages of 51 and 60 were more likely to be taking anti-epileptic medications (Hu Y *et al.* 2017). In our study, we discovered that males with a mean age of ±56.5 years had a considerably higher prevalence rate. Men had a slightly greater incidence rate of epilepsy than women, according to several studies. Additionally, compared to women, men may be more susceptible to injury-induced seizures. Because of their work, exposure to risk factors, head trauma, and alcohol usage, men are more likely to develop epilepsy. One important explanation for gender variations may be steroid hormones.

The precise biological cause, which needs more research, has not been identified in the earlier literature. Identifying risk factors for epilepsy is crucial for understanding its pathophysiology and

developing effective prevention strategies. Additionally, our study revealed that patients had other risk factors such as hypertension, type 2 diabetes mellitus, IHD and CVA which can contribute to the morbidity and mortality factors. Severe illnesses can trigger seizures by altering metabolic levels, causing fever, sleep deprivation, and other conditions. Our findings support the notion that COVID-19 hospitalized patients had a little higher incidence of epilepsy or seizures compared to non-infected individuals. Our study found that lockdowns had a significant detrimental influence on PwE's mental health, including sleep disruptions, despair, and anxiety. Moderate and severe anxiety levels were linked to worsened seizures. Our study's primary drawback is that it only involved one location; as a result, it is unlikely that the results can be applied to India. A few characteristics, including the patients' compliance and quality of life with continued treatment, have not been evaluated because this study also contains retrospective analysis. It is yet unclear how patients who have seizures after COVID-19 will fare in the long run. Furthermore, we did not compare the likelihood of epilepsy and seizures in the general population with the likelihood of epilepsy following COVID-19 vaccination.

CONCLUSION: Epilepsy treatment primarily focuses on minimizing seizure frequency through judicious antiepileptic drug (AED) use. However, challenges arise from drug-related issues such as adverse interactions, side effects, and toxicity, hindering optimal treatment. During COVID-19 treatment, concurrent AED use necessitates careful evaluation of potential drug interactions to prevent adverse outcomes like toxicity or treatment failure. People with epilepsy were more vulnerable during the COVID-19 pandemic, with hospitalization risks rising by 60% and mortality risks by 33%. Interestingly, new epilepsy diagnoses declined during the pandemic, alongside decreased emergency department visits, hospital admissions, and outpatient appointments for epilepsy. While epilepsy-related deaths slightly increased, non-COVID-19 deaths decreased. Notably, no surge in severe seizures (status epilepticus) occurred.

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