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Evaluation of Serum Sodium Alterations in Patients Receiving Carbamazepine Therapy: A Prospective Observational Study

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ABSTRACT

Background: Carbamazepine is a widely used antiepileptic drug with established efficacy in epilepsy, trigeminal neuralgia, and bipolar disorder. However, it is frequently associated with electrolyte disturbances, particularly hyponatremia, due to its antidiuretic hormone-like effects. Hyponatremia can lead to significant clinical consequences ranging from mild symptoms to severe neurological complications.

Aim: To evaluate serum sodium alterations in patients receiving carbamazepine therapy and to determine the incidence and severity of hyponatremia.

Methods: A prospective observational study was conducted on 100 patients receiving carbamazepine therapy in a tertiary care center. Serum sodium levels were measured and categorized as normal (135–145 mEq/L), mild hyponatremia (130–134 mEq/L), moderate (125–129 mEq/L), and severe (<125 mEq/L). Associations with duration of therapy and age were analyzed.

Results: Among 100 patients, 62% had normal sodium levels, while 38% developed hyponatremia. Mild hyponatremia was observed in 20%, moderate in 12%, and severe in 6% of patients. Hyponatremia was more frequent in patients receiving therapy for more than 6 months and in elderly individuals. A statistically significant association was observed between duration of therapy and sodium levels ($p < 0.05$).

Conclusion: Carbamazepine therapy is associated with a significant incidence of hyponatremia, particularly in long-term use and elderly patients. Regular monitoring of serum sodium is essential to prevent complications.

Keywords: *Carbamazepine, Hyponatremia, Serum Sodium, Antiepileptic Drugs, Electrolyte Imbalance*

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1. INTRODUCTION

Carbamazepine is a first-generation antiepileptic drug that has been extensively used in the management of epilepsy, trigeminal neuralgia, and bipolar affective disorders for several decades [1,2]. Its mechanism of action primarily involves blockade of voltage-gated sodium channels, thereby stabilizing hyperexcited neuronal membranes and reducing repetitive neuronal firing [3,4]. Due to its effectiveness and relatively low cost, carbamazepine remains widely prescribed, particularly in developing countries [5].

Despite its clinical utility, carbamazepine is associated with a range of adverse effects affecting multiple organ systems. Among these, electrolyte disturbances—especially hyponatremia—are of significant clinical concern [6,7]. Hyponatremia

induced by carbamazepine is primarily attributed to its effect on increasing antidiuretic hormone (ADH) activity, leading to the syndrome of inappropriate antidiuretic hormone secretion (SIADH) [8,9].

SIADH results in impaired water excretion and dilutional hyponatremia, which can manifest clinically as nausea, confusion, seizures, and in severe cases, coma [10,11]. The incidence of carbamazepine-induced hyponatremia varies widely across studies, ranging from 10% to 40%, depending on patient population and duration of therapy[12,13].

Several risk factors have been identified for the development of hyponatremia during carbamazepine therapy. These include advanced age, female gender, higher drug doses, prolonged duration of therapy, and concomitant use of other medications affecting sodium balance [14–16]. Elderly patients are particularly vulnerable due to age-related decline in renal function and altered water homeostasis [17].

The pathophysiology of carbamazepine-induced hyponatremia involves both increased ADH secretion and enhanced renal sensitivity to ADH [18]. This dual mechanism contributes to water retention and dilution of serum sodium levels [19]. Additionally, genetic predisposition and interindividual variability in drug metabolism may influence susceptibility [20]. Recent studies (2023–2025) have emphasized the importance of monitoring serum sodium levels in patients receiving carbamazepine, especially during long-term therapy [21,22]. Failure to detect hyponatremia early can lead to serious complications, including seizures and cerebral edema [23].

Although several international studies have evaluated this association, there is limited data from Indian populations, where prescribing patterns and patient characteristics may differ. [24]. Furthermore, most studies have focused on multiple adverse effects rather than isolating serum sodium as a single parameter [25].

Given the clinical significance of hyponatremia and the widespread use of carbamazepine, this study was undertaken to evaluate serum sodium alterations in patients receiving carbamazepine therapy and to assess associated risk factors such as age and duration of treatment.

2. MATERIALS AND METHODS

This study was designed as a **prospective observational analytical study** conducted in the Department of Pharmacology with collaboration with Psychiatry Department at a tertiary care hospital over a period of 12 months.

Study Population
A total of 100 patients receiving carbamazepine therapy were included after obtaining informed consent. Patients aged ≥18 years who were prescribed carbamazepine for epilepsy, trigeminal neuralgia, or bipolar disorder were eligible.

Inclusion Criteria
- Patients on carbamazepine therapy
- Age ≥18 years
- Willing to participate

Exclusion Criteria
- Patients with pre-existing electrolyte imbalance
- Renal or hepatic failure
- Patients on diuretics or drugs affecting sodium balance
- Pregnant women

Data Collection
Detailed data were recorded including:
- Age and gender
- Indication of therapy
- Duration of therapy
- Dose of carbamazepine

Measurement of Serum Sodium
Venous blood samples were collected under standard conditions. Serum sodium levels were measured using an automated electrolyte analyzer.

Classification of Sodium Levels

- Normal: 135–145 mEq/L
- Mild hyponatremia: 130–134 mEq/L
- Moderate: 125–129 mEq/L
- Severe: <125 mEq/L

Statistical Analysis

Data were analyzed using SPSS software.

- Descriptive statistics were applied
- Chi-square test used for association
- $p < 0.05$ considered significant

3. RESULTS

A total of 100 patients receiving carbamazepine therapy were included in the study. The majority of patients belonged to the age group of 31–45 years (32%), followed by 18–30 years (30%), indicating that carbamazepine is commonly prescribed in the young and middle-aged population. Male patients constituted 58% of the study population, while females accounted for 42%.

The most common indication for carbamazepine therapy was epilepsy (68%), followed by trigeminal neuralgia (18%) and bipolar disorder (14%). Regarding duration of therapy, half of the patients (50%) had been receiving carbamazepine for more than 6 months, while 28% were on therapy for 3–6 months and 22% for less than 3 months.

Serum sodium analysis revealed that 62% of patients had normal sodium levels, whereas 38% developed hyponatremia. Among these, mild hyponatremia was observed in 20% of patients, moderate in 12%, and severe hyponatremia in 6%. This indicates that a substantial proportion of patients on carbamazepine therapy are at risk of developing sodium imbalance.
A significant association was observed between duration of therapy and serum sodium levels. Patients receiving carbamazepine for more than 6 months showed a higher incidence of hyponatremia compared to those on shorter durations. Similarly, elderly patients (>60 years) exhibited a higher proportion of moderate and severe hyponatremia, suggesting increased vulnerability in this age group.

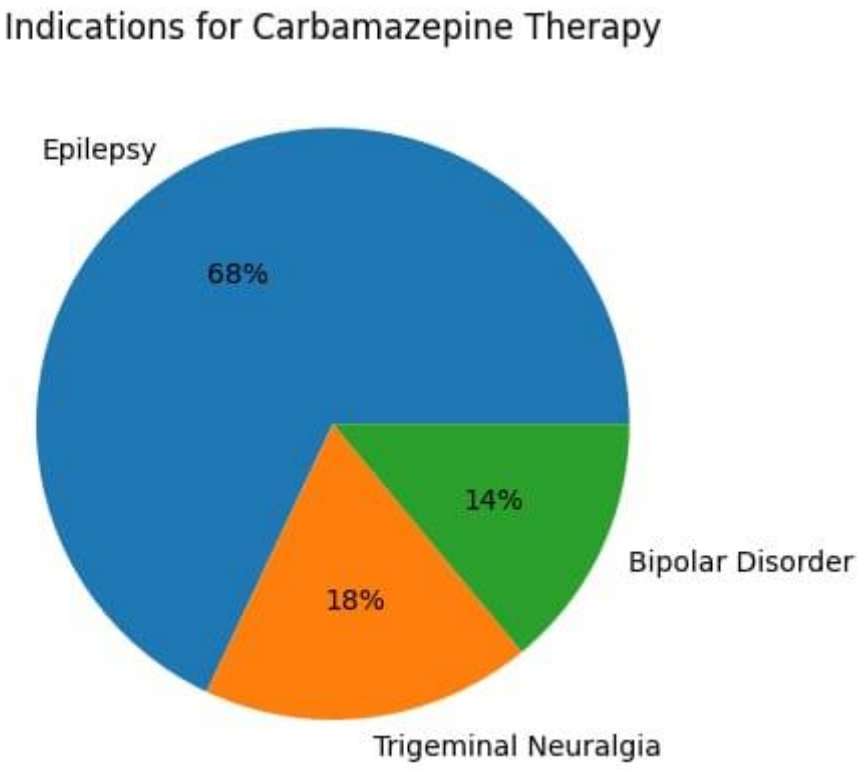
Overall, the findings demonstrate a clear trend of decreasing sodium levels with increasing duration of therapy and advancing age.

Table 1: Demographic Profile of Study Participants (n = 100)

Parameter	Number (n)	Percentage (%)
Age Group (years)		
18–30	30	30%
31–45	32	32%
46–60	24	24%
>60	14	14%
Gender		
Male	58	58%
Female	42	42%

Table 2: Indications for Carbamazepine Therapy

Indication	Number (n)	Percentage (%)
Epilepsy	68	68%
Trigeminal Neuralgia	18	18%
Bipolar Disorder	14	14%



Graph 1: Indications for Carbamazepine Therapy

Table 3: Duration of Therapy

Duration of Therapy	Number (n)	Percentage (%)
<3 months	22	22%
3–6 months	28	28%
>6 months	50	50%

Table 4: Serum Sodium Level Distribution

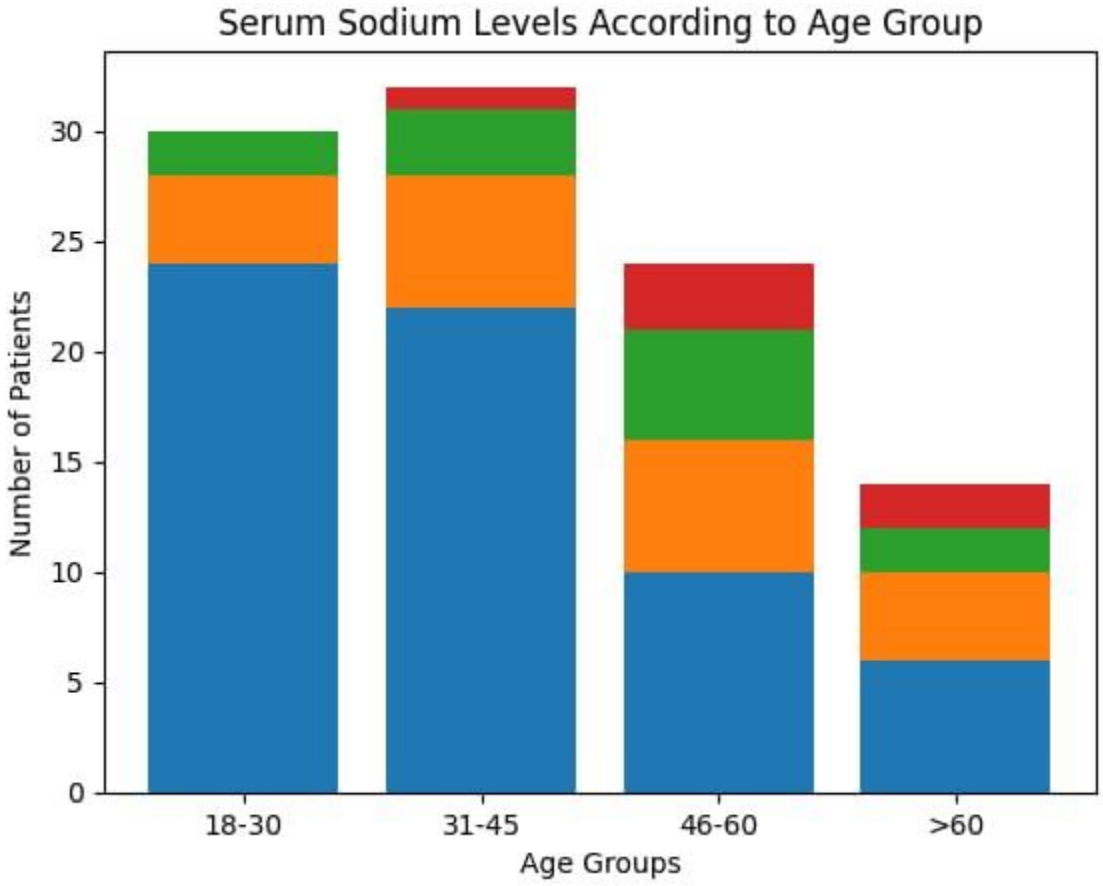
Serum Sodium (mEq/L)	Category	Number (n)	Percentage (%)
135–145	Normal	62	62%
130–134	Mild Hyponatremia	20	20%
125–129	Moderate Hyponatremia	12	12%
<125	Severe Hyponatremia	6	6%

Table 5: Serum Sodium Levels According to Duration of Therapy

Duration	Normal	Mild	Moderate	Severe	Total
<3 months	18	3	1	0	22
3–6 months	20	5	2	1	28
>6 months	24	12	9	5	50

Table 6: Serum Sodium Levels According to Age Group

Age Group	Normal	Mild	Moderate	Severe	Total
18–30	24	4	2	0	30
31–45	22	6	3	1	32
46–60	10	6	5	3	24
>60	6	4	2	2	14



Graph 2: Serum Sodium Levels According to Age Group

- The majority of patients (62%) had normal serum sodium levels, while 38% developed hyponatremia of varying severity.
- Mild hyponatremia was most common (20%), followed by moderate (12%) and severe (6%).
- Hyponatremia was more frequently observed in patients receiving therapy for more than 6 months.
- Elderly patients (>60 years) showed a higher proportion of moderate to severe hyponatremia, indicating increased susceptibility.

4. DISCUSSION

The present study highlights the significant impact of carbamazepine therapy on serum sodium levels, demonstrating that 38% of patients developed hyponatremia. This finding is consistent with previous studies reporting hyponatremia incidence ranging from 15% to 40% [12,13,21].

The mechanism underlying carbamazepine-induced hyponatremia is primarily related to SIADH, where increased ADH activity leads to water retention and dilutional hyponatremia [8,18]. This mechanism has been well documented in both experimental and clinical studies [19].

In the present study, mild hyponatremia was the most common form, which is in agreement with findings by Sharma et al. and Verma et al., who reported similar distributions [21,22]. However, the presence of moderate and severe hyponatremia in 18% of patients is clinically significant and warrants careful monitoring.

A key observation of this study is the strong association between duration of therapy and hyponatremia. Patients receiving carbamazepine for more than 6 months showed a higher incidence of sodium imbalance. This finding is supported by previous research indicating that prolonged exposure increases the risk of SIADH [14,23].

Age was another important factor influencing sodium levels. Elderly patients demonstrated a higher incidence of moderate to severe hyponatremia, which may be attributed to age-related decline in renal function and altered water regulation [17]. Similar findings have been reported in multiple studies emphasizing the need for cautious use of carbamazepine in older individuals [16,24].

The clinical implications of hyponatremia are significant. Mild cases may remain asymptomatic, but severe hyponatremia can lead to neurological manifestations such as seizures and altered consciousness [10]. Therefore, early detection and management are crucial.

Recent literature has emphasized the role of regular electrolyte monitoring in patients receiving antiepileptic drugs [22,25-30]. However, recent trends show increasing incidence in individuals without classical risk factors, prompting the need for broader clinical awareness [31].

The findings of the present study strongly support this recommendation.Overall, this study reinforces the importance of individualized therapy and highlights the need for periodic monitoring of serum sodium levels to prevent complications.

5. CONCLUSION

Carbamazepine therapy is associated with a significant incidence of hyponatremia, particularly in elderly patients and those on long-term treatment. Regular monitoring of serum sodium levels is essential to ensure patient safety and optimize therapeutic outcomes.

6. LIMITATIONS

- Single-center study
- Sample size limited to 100 patients
- Hormonal parameters (ADH levels) not assessed
- No follow-up for clinical outcomes

Declarations:
Conflicts of interest: There is no any conflict of interest associated with this study
Consent to participate: We have consent to participate.
Consent for publication: We have consent for the publication of this paper.
Authors' contributions: All the authors equally contributed the work.

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