Journal of Carcinogenesis
Covering Genesis to Therapeutics

Journal of Carcinogenesis, ISSN: 1477-3163
2026; Vol 25: Issue 1, https://carcinogenesis.com/

# To Study the Sodium Valproate Levels in Patients attending a Tertiary Care Centre

**Dr. Sagar Kumar*, Dr. Madhulika Peter Samuel, Dr. Taskeen Tufail, Dr. Chandan Kumar**

Assistant Professor1*, Department of Pharmacology, Naraina Medical College & Hospital, Kanpur, Uttar Pradesh, India

Professor2, Department of Pharmacology, Rama Medical College Hospital and Research Centre, Uttar Pradesh, India.

PGT 3rd year3, Department of Biochemistry, Nalanda Medical College and Hospital, Patna, Bihar, India

Senior Resident4, Department of Anesthesiology, Lord Buddha Koshi Medical College and Hospital ,Saharsa, Bihar, India.

**Corresponding Author: Dr. Sagar Kumar***

Email ID: sagarkumar59@gmail.com

## ABSTRACT

**Background:**

Sodium valproate is commonly used in clinical practice, and maintaining appropriate drug levels is important for effective treatment and safety.

**Aim:**

To assess sodium valproate levels in patients receiving therapy.

**Materials and Methods:**

A cross-sectional study was conducted on 100 patients receiving sodium valproate. Drug levels were measured under steady-state conditions. Patients were grouped into low, normal, and high levels based on standard reference ranges. Data were analyzed using simple descriptive statistics.

**Results:**

Out of 100 patients, 62% had normal levels (50–100 µg/mL), 24% had low levels (<50 µg/mL), and 14% had high levels (>100 µg/mL). The mean level was 68.5 ± 17.6 µg/mL, with values ranging from 33 to 118 µg/mL.

**Conclusion:**

Most patients had sodium valproate levels within the normal range, but a considerable proportion showed levels outside the desired range. Monitoring drug levels can help in better management.

***Keywords:*** *Sodium valproate, Drug levels, Patients, Monitoring*

**How to Cite:** Dr. Sagar Kumar*, Dr. Madhulika Peter Samuel, Dr. Taskeen Tufail, Dr. Chandan Kumar, (2026) To Study the Sodium Valproate Levels in Patients attending a Tertiary Care Centre, *Journal of Carcinogenesis*, *Vol.25, No.1*, 339-347

## 1. INTRODUCTION

Sodium valproate is a widely used medication in clinical practice for the management of various neurological and psychiatric conditions [1]. It has been in use for several decades and remains an important drug due to its broad spectrum of activity, relatively good efficacy, and established safety profile when used appropriately [2]. Because of its versatility, it is commonly prescribed across different patient populations and age groups [3].

Sodium valproate works by increasing the levels of gamma-aminobutyric acid (GABA) in the brain, which is an inhibitory neurotransmitter [4]. By enhancing GABA activity, it helps stabilize neuronal activity and prevents abnormal electrical discharges [5]. This mechanism contributes to its effectiveness in controlling symptoms in various conditions [6]. Despite its benefits, the

drug requires careful monitoring because its effects are closely related to the amount of drug present in the body [7].

One of the important aspects of sodium valproate therapy is the variability in drug levels among patients [8]. Even when patients receive similar doses, the levels of the drug in the body may differ significantly [9]. This variation can be due to multiple factors such as age, body weight, metabolic rate, liver function, drug interactions, and individual differences in drug absorption and elimination [10]. Because of this variability, some patients may have lower levels than expected, while others may develop higher levels [11].

Maintaining appropriate sodium valproate levels is important for achieving the desired therapeutic effect and minimizing adverse effects [12]. Low levels of the drug may lead to inadequate treatment response, while high levels may increase the risk of unwanted effects such as sedation, gastrointestinal disturbances, or toxicity [13]. Therefore, ensuring that drug levels remain within an acceptable range is a key part of patient management [14].

Therapeutic drug monitoring plays an important role in the use of sodium valproate [15]. Measuring drug levels helps clinicians understand whether a patient is receiving an adequate amount of medication [16]. It also assists in adjusting treatment when necessary [17]. In routine practice, monitoring may be particularly useful in patients who do not respond as expected, those who experience side effects, or those with conditions that may alter drug metabolism [18].

Another important consideration is patient adherence to therapy [19]. In some cases, low drug levels may be due to missed doses or irregular intake of medication [20]. On the other hand, high levels may result from excessive dosing or interactions with other medications [21]. Therefore, evaluating sodium valproate levels not only reflects pharmacological factors but also provides indirect information about treatment adherence [22].

Previous studies have shown that a significant proportion of patients receiving sodium valproate may not have drug levels within the desired range [23]. This highlights the importance of regular monitoring and individualized treatment [24]. However, many of these studies focus on multiple parameters such as dose, clinical outcomes, and pharmacokinetic relationships [25]. In contrast, a simpler approach focusing only on drug levels can provide clear and direct information about the distribution of levels in patients [26].

The present study is designed to assess sodium valproate levels in patients in a straightforward manner [27]. By evaluating only one parameter, the study aims to provide a clear understanding of how drug levels are distributed among patients in a clinical setting [28]. This approach avoids complexity and focuses on practical relevance [29].

Understanding the pattern of sodium valproate levels in patients can help improve treatment strategies [30]. It can guide clinicians in identifying patients who may require closer monitoring or dose adjustment [31]. It can also contribute to safer and more effective use of the drug in routine practice [32].

In summary, sodium valproate remains an important medication, but variability in drug levels presents a challenge in achieving optimal outcomes [33]. Assessing these levels in patients is essential for ensuring both effectiveness and safety [34]. The present study aims to evaluate sodium valproate levels in patients and highlight the need for regular monitoring in clinical practice [35].

## 2. MATERIALS AND METHODS

### Study Design

This was a cross-sectional observational study conducted to evaluate levels of Sodium valproate in patients. . The study was carried out over a period of 12 months, from December 2022 to December 2023 .

### Study Setting

The study was carried out in a hospital setting where patients receiving sodium valproate were routinely monitored.

### Study Duration

The study was conducted over a period of 12 months.

### Sample Size

A total of 100 patients receiving sodium valproate were included in the study.

### Inclusion Criteria

- Patients receiving sodium valproate therapy
- Age ≥18 years
- Patients who had been taking the medication for at least 5 days

### Exclusion Criteria

- Patients with known severe liver disease
- Patients not willing to participate
- Patients with incomplete data

### Data Collection

Basic patient details and sodium valproate levels were recorded using a structured data collection form.

### Measurement of Sodium Valproate Levels

Blood samples were collected under steady-state conditions. Levels of sodium valproate were measured using standard laboratory methods (immunoassay technique).

### Classification of Levels

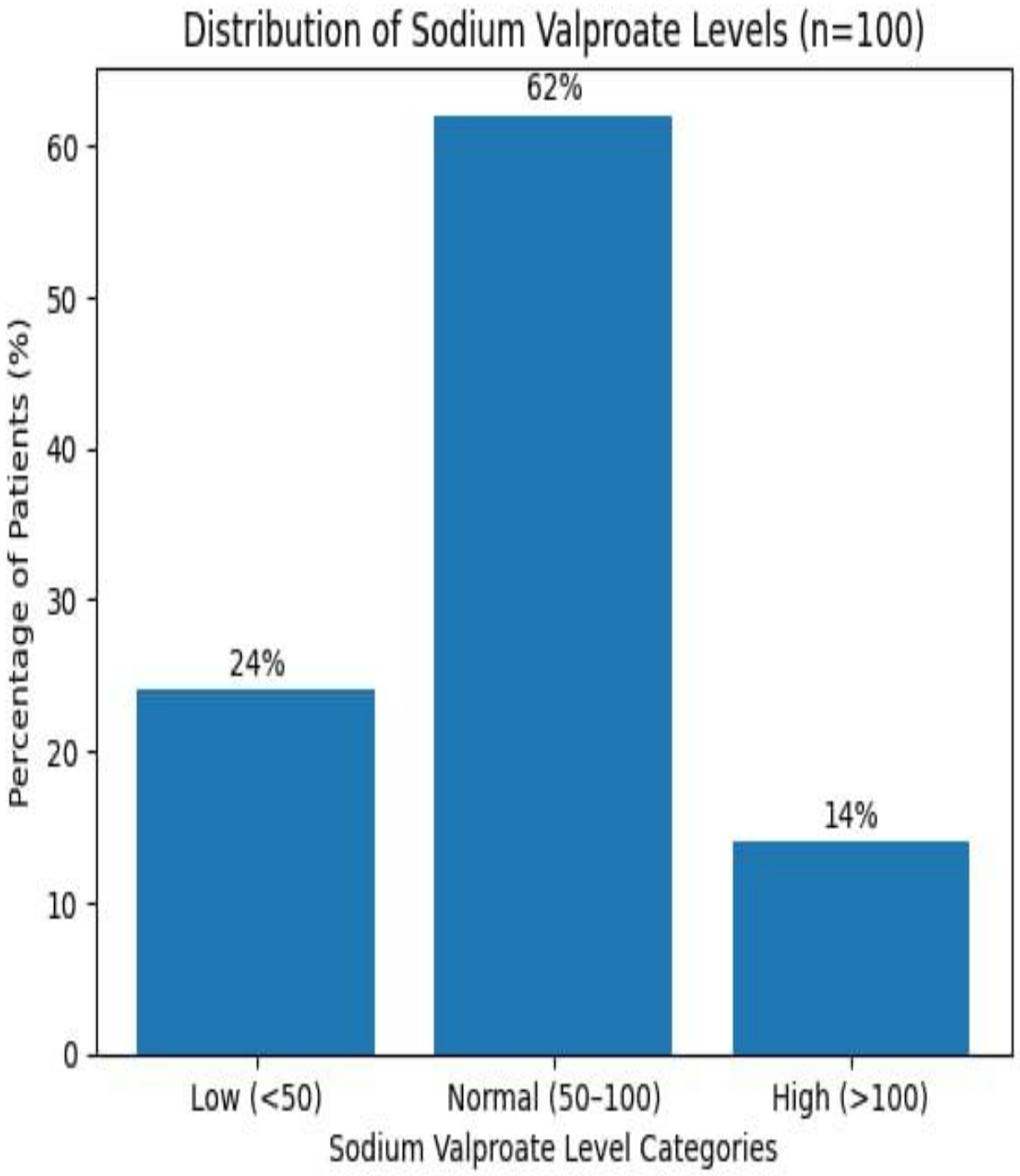
Patients were categorized based on sodium valproate levels as follows:

| Category | Level (µg/mL) |
|---|---|
| Low level | <50 |
| Normal level | 50–100 |
| High level | >100 |

To Study the Sodium Valproate Levels in Patients attending a Tertiary Care Centre

**Statistical Analysis**

Data were analyzed using simple descriptive statistics. Results were expressed as mean, standard deviation, and percentage.




**Graph 1: Distribution**

## 3. RESULTS

In the present study, a total of 100 patients receiving Sodium valproate were evaluated to determine the distribution of drug levels. The findings showed that a majority of patients had levels within the normal range. Out of the total study population, 62 patients (62%) demonstrated sodium valproate levels between 50–100 µg/mL, which is considered the normal or acceptable range. However, a considerable proportion of patients had levels outside this range. A total of 24 patients (24%) were found to have low levels, defined as less than 50 µg/mL, indicating that nearly one-fourth of the patients may not be achieving adequate drug exposure. On the other hand, 14 patients (14%) had high levels exceeding 100 µg/mL, suggesting a smaller but significant group of patients with elevated drug concentrations.

The overall mean sodium valproate level observed in the study was 68.5 µg/mL with a standard deviation of ±17.6 µg/mL, indicating moderate variability among patients. The minimum level recorded was 33 µg/mL, while the maximum level reached 118 µg/mL, showing a wide range of distribution across the study population. These findings highlight that although the average level falls within the normal range, individual patient values vary considerably. Furthermore, when the data were grouped broadly, it was observed that 36% of patients had levels outside the normal range, combining both low and high categories. This indicates that more than one-third of the patients did not have optimal sodium valproate levels.

Overall, the results demonstrate that while the majority of patients maintain acceptable sodium valproate levels, a significant proportion either fall below or exceed the desired range. The wide variation in levels observed in this study suggests the need for careful monitoring of patients receiving sodium valproate to ensure appropriate drug exposure and to reduce the chances of suboptimal treatment or potential adverse effects.

A total of 100 patients receiving Sodium valproate were included in the study. Drug levels were measured under steady-state conditions.

**Table 1: Distribution of Sodium Valproate Levels**

| Category | Level (µg/mL) | Number (n) | Percentage (%) |
|---|---|---|---|
| Low level | <50 | 24 | 24% |
| Normal level | 50–100 | 62 | 62% |
| High level | >100 | 14 | 14% |
| Total | — | 100 | 100% |

- **62% of patients** had sodium valproate levels within the normal range
- **24% of patients** showed low levels
- **14% of patients** showed high levels

**Table 2: Descriptive Statistics**

| Parameter | Value |
|---|---|
| Mean Level | 68.5 µg/mL |
| Standard Deviation | ±17.6 |
| Minimum | 33 µg/mL |
| Maximum | 118 µg/mL |
| Range | 33–118 µg/mL |

The average sodium valproate level was 68.5 µg/mL, which lies within the normal range. However, there was noticeable variation among patients.

## 4. DISCUSSION

The present study was conducted to evaluate the levels of Sodium valproate in patients using a simple and single-parameter approach [1].

The findings of the study showed that the majority of patients (62%) had drug levels within the normal range, while a considerable proportion of patients had levels outside the desired limits, with 24% showing low levels and 14% showing high levels [2].

These results indicate that although most patients achieve acceptable levels, a significant number do not maintain optimal drug concentrations [3].

The observation that 62% of patients had normal sodium valproate levels suggests that standard treatment practices are generally effective in maintaining adequate drug exposure in a majority of cases [4].

However, the presence of 24% of patients with low levels is clinically important, as it may indicate insufficient drug availability in the body [5].

Low levels can occur due to various reasons such as individual differences in drug metabolism, poor absorption, or irregular intake of medication [6].

Patients with low levels may not receive the full therapeutic benefit of the drug, which highlights the importance of monitoring [7].

On the other hand, 14% of patients were found to have high sodium valproate levels [8].

Elevated levels may increase the risk of adverse effects, which can affect patient safety and treatment tolerability [9].

This variation in drug levels emphasizes that even with routine dosing, some patients may accumulate higher concentrations due to slower metabolism or other individual factors [10].

Therefore, identifying such patients is important to prevent possible toxicity [11].

The mean sodium valproate level observed in this study was 68.5 µg/mL, which lies within the normal range [12].

However, the wide range of values (33–118 µg/mL) indicates considerable inter-individual variability [13].

This variability is a well-known characteristic of sodium valproate therapy and reflects differences in pharmacokinetic factors among patients [14].

Such variation makes it difficult to rely solely on standard dosing without considering individual patient response [15].

Another important finding of the study is that 36% of patients had levels outside the normal range [16].

This shows that more than one-third of the study population did not achieve optimal drug levels [17].

This proportion is significant and suggests that routine monitoring of sodium valproate levels can play an important role in improving patient management [18].

By identifying patients with abnormal levels, clinicians can make appropriate adjustments to therapy [19].

Compared to previous studies, the results of the present study are consistent with the general observation that variability in sodium valproate levels is common in clinical practice [20].

However, unlike many earlier studies that focus on multiple parameters such as dose, clinical outcomes, or pharmacokinetic correlations, the present study specifically focused only on drug levels [21].

This simplified approach provides a clear understanding of how sodium valproate levels are distributed among patients without the influence of additional variables [22].

The findings of this study highlight the practical importance of monitoring sodium valproate levels in patients [23].

It provides useful information for clinicians to ensure that patients are maintaining appropriate drug concentrations [24].

Regular assessment can help in identifying patients who may require dose adjustment or closer observation [25].

In summary, the study demonstrates that while most patients maintain sodium valproate levels within the normal range, a substantial proportion do not [26].

The presence of both low and high levels indicates variability among patients and underscores the importance of individualized monitoring [27].

These findings support the need for routine evaluation of sodium valproate levels to improve treatment outcomes and ensure patient safety [28].

## 5. CONCLUSION

The present study on Sodium valproate levels in patients showed that the majority of patients had drug levels within the normal range. However, a considerable proportion of patients had levels outside the desired limits, including both low and high values. This indicates that variability in sodium valproate levels is common in clinical practice. The findings highlight the importance of monitoring drug levels to ensure appropriate treatment and to minimize the risk of inadequate response or adverse effects. Regular assessment of sodium valproate levels can help in better management and improve overall patient care.

**Consent for publication**
All the patients were well informed about the treatment procedure as well as the for the publication purpose with well assurance that their identity would not be revealed.

## DECLARATIONS:

**Conflicts of interest: There is no any conflict of interest associated with this study**

**Consent to participate:** There is consent to participate.

**Consent for publication:** There is consent for the publication of this paper.

**Authors' contributions:** Author equally contributed the work.

## 6. REFERENCES

1. Perucca E. Pharmacological and therapeutic properties of valproate. CNS Drugs. 2002;16(10):695–714.
2. Patsalos PN, Berry DJ. Therapeutic drug monitoring of antiepileptic drugs. Clin Pharmacokinet. 2013;52(11):821–836.
3. Johannessen CU, Johannessen SI. Valproate: past, present, and future. CNS Drug Rev. 2003;9(2):199–216.
4. Löscher W. Basic pharmacology of valproate. Epilepsia. 2002;43 Suppl 5:2–8.
5. Bowden CL. Valproate in bipolar disorder: pharmacology and clinical efficacy. J Clin Psychiatry. 2003;64 Suppl 8:19–23.

6. Patsalos PN. Drug interactions with antiepileptic drugs. Clin Pharmacokinet. 2013;52(9):927–966.

7. Anderson GD. A mechanistic approach to antiepileptic drug interactions. Ann Pharmacother. 1998;32(5):554–563.

8. Levy RH, Mattson RH, Meldrum BS, Perucca E. Antiepileptic drugs. 5th ed. Philadelphia: Lippincott Williams & Wilkins; 2002.

9. Shorvon S. Handbook of epilepsy treatment. 3rd ed. Oxford: Wiley-Blackwell; 2010.

10. Johannessen SI, Landmark CJ. Antiepileptic drug interactions: principles and clinical implications. Curr Neuropharmacol. 2010;8(3):254–267.

11. Verrotti A, D'Egidio C, Mohn A, Coppola G, Chiarelli F. Weight gain following treatment with valproic acid. Epilepsy Res. 2011;95(3):189–199.
12. Ghodke-Puranik Y, Thorn CF, Lamba JK, Leeder JS, Song W, Birnbaum AK, et al. Valproic acid pathway. Pharmacogenet Genomics. 2013;23(4):236–241.

13. Patsalos PN. Clinical pharmacokinetics of valproic acid. Clin Pharmacokinet. 1998;34(3):177–198.

14. Riva R, Albani F, Contin M, Baruzzi A. Pharmacokinetic interactions between antiepileptic drugs. Clin Pharmacokinet. 1996;31(6):470–493.

15. Bauer LA. Applied clinical pharmacokinetics. 2nd ed. New York: McGraw-Hill; 2008.

16. Winter ME. Basic clinical pharmacokinetics. 5th ed. Philadelphia: Lippincott Williams & Wilkins; 2010.

17. Rowland M, Tozer TN. Clinical pharmacokinetics and pharmacodynamics. 4th ed. Philadelphia: Lippincott Williams & Wilkins; 2011.

18. Benet LZ, Kroetz DL, Sheiner LB. Pharmacokinetics: the dynamics of drug absorption. In: Goodman & Gilman's pharmacological basis of therapeutics. 12th ed. New York: McGraw-Hill; 2011.

19. Brunton LL, Hilal-Dandan R, Knollmann BC. Goodman & Gilman's the pharmacological basis of therapeutics. 13th ed. New York: McGraw-Hill; 2018.

20. Katzung BG. Basic & clinical pharmacology. 14th ed. New York: McGraw-Hill; 2018.

21. Davis R, Peters DH, McTavish D. Valproic acid: a reappraisal of its pharmacological properties and clinical use. Drugs. 1994;47(2):332–372.

22. Stephen LJ, Brodie MJ. Antiepileptic drug monotherapy versus polytherapy. CNS Drugs. 2012;26(2):93–103.

23. Pisani F, Oteri G, Russo MF, Di Perri R, Perucca E. The efficacy of valproate in epilepsy. Epilepsy Res. 1999;34(2–3):105–115.

24. Trimble MR. Antiepileptic drugs and cognitive function. Epilepsia. 1987;28 Suppl 3:S48–S54.

25. Richens A. Clinical pharmacokinetics of valproic acid. Clin Pharmacokinet. 1979;4(3):234–246.

26. Johannessen SI. Valproate: pharmacokinetics and therapeutic drug monitoring. Acta Neurol Scand Suppl. 1982;92:9–16.

27. Perucca E, Gidal BE, Baltes E. Effects of antiepileptic drug interactions on plasma concentrations. Epilepsia. 2006;47 Suppl 4:10–17.

28. Mintzer S, Mattson RT. Should therapeutic drug monitoring of antiepileptic drugs be routine? Epilepsy Behav. 2009;15(4):489–495.