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Original Article

Prescription Patterns and Rational Use of Anti-Seizure Medications in Paediatric Epilepsy: A Prospective Observational Study from A South Indian Tertiary Care Hospital

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Abstract

Objective: To study the prescribing pattern of anti-seizure medications (ASMs) and evaluate for adherence to World Health Organisation/International Network for Rational Use of Drugs (WHO/INRUD) prescribing indicators and also evaluate if the dose was appropriate in a cohort of children with epilepsy at a tertiary care centre in South India.

Methods: A seven-month (February–August 2024) prospective observational study was performed at the Department of Paediatrics, a tertiary care hospital in Erode, Tamil Nadu. Consecutive paediatric patients with International League Against Epilepsy (ILAE) 2017–confirmed epilepsy on ASM therapy were enrolled. The quality of prescribing was assessed using 21 WHO/INRUD indicators across four domains: prescribing, patient care, facility, and complementary. The appropriateness of the dosing was compared to the British National Formulary for Children (BNF-C) reference ranges.

Results: In a cohort of 173 patients (mean age 7.2±4.7 y; male 57.2%; rural residency 67.6%), 248 ASM prescriptions were analysed. Generalised tonic–clonic seizures were most common (39.3%), and the predominant aetiology was idiopathic/genetic (56.6%). Monotherapy was used in 61.8% of cases, with Sodium Valproate (27.4%) and Levetiracetam (19.4%) being the most prescribed drugs. Of the 21 WHO/INRUD indicators evaluated, the following exceeded target benchmarks: number of monotherapy prescriptions and correct dose (89.5%), documented diagnosis (98.8%), TDM (76.3%), and patient knowledge levels concerning treatment (85.0%). Continued deficiencies were observed for generic prescribing (73.0% v 100% goal), National List of Essential Medicines (NLEM) adherence (66.1%), availability of drugs recommended to treat key diseases (68.8%) and affordability (72.8% v>80%). The cumulative under-dosing rate (6.5%) was higher than the over-dosing rate (4.0%). Comorbidities were found in 40.5% of patients.

Conclusion: This analysis shows that ASM prescribing is not so incompatible with the monotherapy and dosage recommendations from previous guidelines, but persistent deficiencies in generic prescribing, formulary adherence and drug affordability remain. Recommendations include targeted interventions, such as including medicines on an essential medicines list, using electronic prescribing, and strengthening the supply chain.

Keywords: Anti-seizure medications, Drug utilisation, Paediatric epilepsy, Prescribing indicators, Rational drug use, WHO/INRUD

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Introduction

Epilepsy is the second most common neurological disorder, afflicting over 50 million individuals worldwide—an even greater burden in children who make up a large proportion of acquired epilepsies and the majority live within low-and middle-income countries (LMICs) [1]. The Global Burden of Disease Study 2021 observed a worldwide prevalence of active epilepsy at 658 per 100,000 population [1]. The 2017 ILAE classification framework, with three diagnostic levels (seizure type, epilepsy type, and epilepsy syndrome) and six aetiological categories at each level, has ensured a standardised approach to both diagnosis and management [2, 3]. Although effective (Anti)Seizure Medications (ASMs) exist, enabling freedom from seizures in as many as 70% of individuals with epilepsy, the World Health Organisation reports that the treatment gap is higher than 75% in low-income countries [4], owing to barriers related to drug availability, shortages of specialists and socio-cultural obstacles. Since the 1990s, more than 20 newer ASMs have been introduced, widening therapeutic opportunities with improved tolerability and pharmacokinetic profiles; however, their effect on seizure freedom rates has been modest overall [5].

India accounts for about one-sixth of the global epilepsy burden with 10–12 million persons with epilepsy, significant rural–urban differentials, and overall prevalence of 3.0–11.9 per 1,000 population [6]. The shortage of essential antiepileptic drugs (ASMs) at 30–40% of primary health centres [6, 7] suggests severe constraints in healthcare infrastructure for paediatric neurology. These limitations, intensified by economic deprivation and social stigma, lead to specific prescribing dilemmas in tertiary care environments where age-associated pharmacokinetic variability, restricted drug selection and cost constraints significantly impact the choice of medicine. Timely optimisation of treatment is vital, as failure of two appropriately selected ASMs leads to a subsequent probability of seizure freedom of less than 5% [8]. However, there is a lack of available data from South India on ASM prescribing practices, compliance with guidelines and rational use of drugs.

This study was therefore designed as a prospective observational study at a tertiary referral hospital in Erode, Tamil Nadu, to systematically evaluate prescribing patterns of ASM for paediatric epilepsy. The objectives of the study were to 1) characterise the distribution of conventional versus newer anti-seizure medication (ASM); 2) assess adherence to WHO/INRUD prescribing indicators; 3) evaluate appropriateness of dosing and polytherapy rates, and 4) identify factors affecting prescriber decision-making. The results aim to provide an evidence base for targeting quality-improvement interventions and to inform context-specific prescribing guidance, thereby optimising paediatric epilepsy management in resource-limited settings.

Materials and Methods

This observational study was conducted in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for 7 mo (February to August 2024) at the Department of Paediatrics, a tertiary care hospital in Erode, Tamil Nadu, which is a referral centre for western Tamil Nadu. The study population included paediatric patients aged 1 mo–18 y diagnosed with epilepsy according to ILAE 2017 classification criteria [2, 3] and undergoing ASM treatment. We also excluded patients with acute symptomatic seizures due to metabolic derangements, central nervous system infections or acute head trauma, febrile seizures, and non-epileptic paroxysmal events as well as neonates younger than one month of age.

Using the single proportion formula ($n=Z^2pq/d^2$) at p=0.50 with a maximum variability, an absolute precision of 6.5% and the 95% confidence level, we calculated the minimum sample size to be 228. During the study period, 173 eligible patients were enrolled through consecutive sampling. Based on this achieved sample size, the absolute precision was recalculated to be 7.5% at a 95% confidence level. The lower-than-expected enrolment reflects the true rate of eligible patients presenting over the study period, rather than premature recruitment cessation. Data collection was performed within 24 h of each clinical encounter through a structured proforma, which was developed according to the guidelines on drug utilisation studies by WHO [9] and included patient demographics, seizure classification, all ASMs prescribed along with generic and brand names, dosage form, frequency and duration of therapy as well as whether they were on monotherapy or polytherapy.

As per the prescription patterns, ASMs were divided into conventional drugs (phenytoin, phenobarbitone, carbamazepine and sodium valproate) and new agents (levetiracetam, oxcarbazepine, topiramate, lamotrigine, clobazam and lacosamide), and prescribed daily doses was compared with standard paediatric dosing ranges (mg/kg/day) [20] defined in BNF for Children (BNF-C 2023–2024). The rational prescribing was evaluated using 21 WHO/INRUD core drug prescribing indicators adapted for ASM evaluation [9], including five prescribing indicators (mean number of drugs per encounter, monotherapy rate, proportion of drugs prescribed by generic name, percentage encounters with an injection prescribed and percentage of drugs from the NLEM), four patient care indicators (mean consultation time, mean dispensing time, proportion of dispensed medicines actually dispensed and patients with adequate knowledge on correct dosage) as well as one facility indicator (availability of key ASMs in hospital pharmacy) and 11 complementary indicators that have been defined between appropriate drug selection, correct paediatric dosing; documented diagnosis; complete dosing instructions; Therapeutic Drug Monitoring(TDM) when indicated; drug–drug interactions; prescription errors and affordability [9]. Data management was performed through double data entry of 20% of randomly selected prescriptions; quality control included weekly review meetings and random confirmation of 10% of the collected forms. IBM SPSS Statistics version 25.0 (IBM Corporation, Armonk, NY, USA) was used to conduct statistical analysis. It was a descriptive study; categorical variables were presented as frequencies and percentages, while continuous variables were expressed as mean±standard deviation or median with interquartile range. No inferential comparisons were pre-specified. Ethical clearance was obtained from the Institutional Ethics Committee of J. K. K. Nattraja College of Pharmacy, Kumarapalayam (JKKNCP/IEC-CER/1926125/2615), which has jurisdiction over research conducted at its associated tertiary care hospital.

Results

Demographic and clinical characteristics

Overall, 173 patients with epilepsy in the paediatric department were included during the 7-month study period (February–August 2024), resulting in 248 ASM prescriptions. Table 1 summarises the patients' demographic and clinical characteristics. The mean age was 7.2±4.7 y (median 6.4; IQR 3.0–10.5), with school-age children (>6-12 y) being the largest group (n=51; 29.5%) followed by preschool (n=39; 22·5%), toddler (n=36; 20·8%), adolescent (n=24; 13·9%) and infant (23,13·3%). 99, 57.2% of the cohort were male (n=99). A total of 67.6% of patients were from rural areas, and the majority belonged to lower socioeconomic strata (Upper, Lower and Lower classes: 61.8%). The mean body weight was 18.5±11.0 kg; 27.2% were underweight and 11.0% overweight, according to the World Health Organisation classification system.

The most common type of seizure was generalised tonic–clonic seizures (n=68; 39.3%), followed by focal seizures (n=52; 30.1%), focal with secondary generalisation (n=21; 12.1%), absence seizures (n=14; 8.1%), myoclonic seizures (n=8; 4.6%), infantile spasms (n=6; 3.5%) and mixed types (n=4; 2.3%). Idiopathic/or genetic aetiology accounted for the most common causes (n=98; 56.6%), followed by structural (n=37; 21.4%), infectious (n=18; 10.4%), metabolic (n=7; 4.0%) and unknown causes (n=13; 7.5%). The average duration of epilepsy at enrolment was 2.1±2.3 y; 23.7% were recently diagnosed (6 mo (8.7%). Electroencephalographic abnormalities were documented in 142 patients (82.1%), of whom 52.1% showed generalised and 40.8% showed focal discharge patterns. Comorbidities were present in 70 patients (40.5%), with developmental delay being the most prevalent (22.0%), followed by cerebral palsy (8.1%), intellectual disability (6.4%), and attention deficit hyperactivity disorder (4.0%). Concomitant Pathologies 70 patients (40.5%) had comorbidities; the most common pathology being developmental delay at a rate of 22.0%, with other diagnoses such as cerebral palsy (8.1%), intellectual disability (6.4%) and attention deficit hyperactivity disorder (4.0%).

Table 1: Demographic and clinical characteristics of the study population (n=173).

Characteristic	n (%) or mean±SD
Demographics	
Age (years), mean±SD; median (IQR)	7.2±4.7; 6.4 (3.0–10.5)
Infant (1 mo–1 y)	23 (13.3)
Toddler (>1–3 y)	36 (20.8)
Preschool (>3–6 y)	39 (22.5)
School age (>6–12 y)	51 (29.5)
Adolescent (>12–18 y)	24 (13.9)
Sex, male/female	99/74 (57.2/42.8)
Body weight (kg), mean±SD	18.5±11.0
Nutritional status	
Underweight/normal/overweight	47 (27.2)/107 (61.8)/19 (11.0)
Residence, rural	117 (67.6)
Socioeconomic status (modified Kuppuswamy scale 2024)	
Upper+upper middle (I–II)	28 (16.2)
Lower middle (III)	38 (22.0)
Upper lower+lower (IV–V)	107 (61.8)
Seizure type (ILAE 2017)	
Generalised tonic–clonic	68 (39.3)
Focal	52 (30.1)

Focal with secondary generalisation	21 (12.1)
Absence	14 (8.1)
Myoclonic	8 (4.6)
Infantile spasms	6 (3.5)
Mixed types	4 (2.3)
Aetiology	
Idiopathic/genetic	98 (56.6)
Structural	37 (21.4)
Infectious	18 (10.4)
Metabolic	7 (4.0)
Unknown	13 (7.5)
Disease characteristics	
Duration of epilepsy (y), mean±SD	2.1±2.3
Newly diagnosed (<3 mo)	41 (23.7)
3–12 mo	38 (22.0)
1–2 y	35 (20.2)
2–5 y	42 (24.3)
>5 y	17 (9.8)
Seizure frequency at presentation	
Daily/weekly/monthly	19 (11.0)/43 (24.9)/57 (32.9)
Occasional (>monthly)	39 (22.5)
Seizure-free (>6 mo)	15 (8.7)
EEG findings and comorbidities	
Abnormal EEG	142 (82.1)
Generalised/focal/other	74 (52.1)/58 (40.8)/10 (7.0)
Any comorbidity	70 (40.5)
Developmental delay	38 (22.0)
Cerebral palsy	14 (8.1)
Intellectual disability	11 (6.4)
ADHD	7 (4.0)

ADHD-Attention Deficit Hyperactivity Disorder; EEG-Electroencephalogram; ILAE=International League Against Epilepsy; IQR-Interquartile range; Mo-Months; Y-Years.

Prescribing patterns and drug selection

The mean number of drugs per encounter was 1.43±0.62, and the monotherapy rate was 61.8% (107/173). Thirty point one per cent (n=52) of patients received therapy with two drugs, and 8.1% (n=14) used three or more drugs. Conventional ASMs accounted for 57.3% of all prescriptions (n=142), and newer agents accounted for the remaining 42.7% (n=106). The most frequently prescribed AED was sodium valproate (n=68; 27.4%), followed by levetiracetam (n=48; 19.4%), phenytoin (n=42; 16.9%), carbamazepine (n=21; 8.5%), oxcarbazepine (n=19; 7.7%), clobazam (n=16; 6.5%) topiramate (n=12; 4.8%) phenobarbitone (n=11; 4.4%) lamotrigine(n=8; 3.2%) and lacosamide(n=3; 1.2%).

In total, 66 patients (38.2%) were on polytherapy; this subgroup was characterised by a higher percentage of structural aetiology (33.3% vs 14.0% of monotherapy group), longer mean duration of epilepsy (3.4±2.5 y vs 1.3±1.6 y) and greater seizure frequency at presentation; 21.2% had daily seizures compared with only 4.7% among those who received monotherapy management.' Comorbidities were also more common in the polytherapy subgroup (57.6% vs 29.9%), especially developmental delay and cerebral palsy. These results are consistent with the known relationship between polytherapy requirement and indices of therapeutic complexity, such as refractoriness and structural brain damage [18].

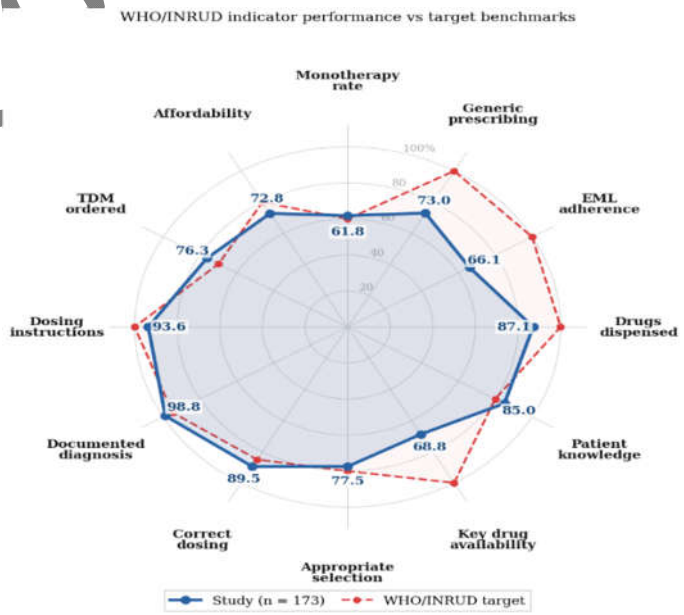

Fig. 1: Radar chart comparing study performance against WHO/INRUD target benchmarks across 12 prescribing quality indicators in paediatric epilepsy (n=173). Each axis represents one prescribing quality indicator expressed as a percentage; the shaded area represents observed performance, and the outer boundary represents the WHO/INRUD benchmark target.

Table 2: Assessment of prescribing quality using WHO/INRUD indicators and dosing analysis (N=173 patients; 248 prescriptions)

Indicator	Study value	WHO target
Prescribing indicators		
Average drugs per encounter	1.43±0.62	<2.0
Monotherapy rate	107/173 (61.8%)	>60%
Drugs prescribed by generic name	181/248 (73.0%)	100%
Encounters with injection	8/173 (4.6%)	<10%
Drugs from NLEM 2022	164/248 (66.1%)	100%
Conventional ASM preference	142/248 (57.3%)	—
Patient care indicators		
Average consultation time (min)	12.4±4.2	>10
Average dispensing time (min)	3.8±1.2	>3
Drugs actually dispensed	216/248 (87.1%)	100%
Patients with adequate knowledge	147/173 (85.0%)	>80%
Facility indicator		
Availability of key ASMs	11/16 (68.8%)	100%
Complementary indicators		
Appropriate drug selection	134/173 (77.5%)	>80%
Correct paediatric dosing[a]	222/248 (89.5%)	>85%
Documented diagnosis	171/173 (98.8%)	>95%
Complete dosing instructions	162/173 (93.6%)	100%
TDM ordered when indicated	58/76 (76.3%)	>70%
Drug–drug interactions	14/173 (8.1%)	<10%
Prescription errors	35/173 (20.2%)	<25%
Affordability (<20% income)	126/173 (72.8%)	>80%

ASM-Antiseizure Medication; NLEM-National List of Essential Medicines; TDM-Therapeutic Drug Monitoring; WHO/INRUD-World Health Organization/International Network for Rational Use of Drugs; [a]Dose within ±10% of recommended weight-based range per current guidelines.

Table 3: Dosing appropriateness by antiseizure medication.

Drug	n	Range[a]	Mean±SD[a]	Appropriate	Under/over
Sodium valproate	68	15–40	22.8±7.2	62 (91.2)	4 (5.9)/2 (2.9)
Levetiracetam	48	20–60	32.5±10.8	45 (93.8)	2 (4.2)/1 (2.1)
Phenytoin	42	4–8	5.6±1.8	37 (88.1)	3 (7.1)/2 (4.8)
Carbamazepine	21	10–20	14.2±4.5	18 (85.7)	2 (9.5)/1 (4.8)
Oxcarbazepine	19	10–30	18.6±6.2	17 (89.5)	1 (5.3)/1 (5.3)
Clobazam	16	0.25–0.75	0.42±0.15	14 (87.5)	1 (6.3)/1 (6.3)
Topiramate	12	2–6	4.2±1.8	10 (83.3)	1 (8.3)/1 (8.3)
Phenobarbitone	11	3–5	3.8±1.2	9 (81.8)	1 (9.1)/1 (9.1)
Lamotrigine[b]	8	2–5	3.8±1.5	7 (87.5)	1 (12.5)/0 (0.0)
Lacosamide	3	4–8	6.5±2.1	3 (100.0)	0 (0.0)/0 (0.0)
Total	248	—		222 (89.5)	16 (6.5)/10 (4.0)

Value are n (%) or mean±SD. [a]Recommended dose range and prescribed dose expressed in mg/kg/day. [b]Lamotrigine dose range applies in the absence of concomitant valproate. ASM=antiseizure medication, WHO/INRUD=World Health Organisation/International Network for Rational Use of Drugs.

WHO/INRUD prescribing indicators

The WHO/INRUD-wise prescribing indicators are reported in table 2. Of the 21 assessed indicators across the prescribing, patient care, facility, and complementary domains, 11 were at or above their associated WHO target benchmark (table 2). Among the prescribing indicators, the monotherapy rate (61.8%) exceeded the>60% target; injection use was low (4.6% vs<10% target), Dispensing time (3.8±1.2 min>3 min) and Patients' knowledge (85%>80%) achieved targets while drugs actually dispensed that was below 100%(87.1%). Availability of key ASMs at the facility pharmacy was 68.8% (11/16 formulations). Among complementary indicators, documented diagnosis (98.8% vs>95%), correct dosing (89.5% vs>85%), TDM when indicated (76.3% vs>70%), drug–drug interactions (8.1% vs<10% target) complete dosing instructions (93.6%, versus 100) and affordability (72.8 %, versus>80%) did not meet targets [32]. Fig. 1 displays a radar chart comparing the 12-core quality-outcome indicators to WHO benchmarks.

Dosing appropriateness

Dosing appropriateness, assessed against BNF for Children reference ranges (mg/kg/day), revealed that 222 of 248 prescriptions (89.5%) were dosed within the appropriate therapeutic range, 16 (6.5%) were under-dosed, and 10 (4.0%) were over-dosed (table 3). Levetiracetam had the highest rate of appropriate dosing (93.8%), followed by sodium valproate (91.2%) and oxcarbazepine (89.5%). Phenobarbitone (81.8%) and topiramate (83.3%) had the lowest rates of dose appropriateness. Underdosing was more prevalent than overdosing across all individual ASMs. Affordability, defined as treatment cost below 20% of household income, was met in 72.8% of patients, falling short of the WHO target of>80%.

Discussion

Thus, this prospective observational study is the first to provide a detailed insight into antiepileptic drug (AED) prescription patterns and rationality indices of AED use in children with epilepsy at a tertiary care centre in South India. The main findings show that out of the total 21 WHO/INRUD indicators, 11 met target benchmarks, highlighting particular strengths in monotherapy practice, appropriateness of dosing given to patients at certain levels, documentation (diagnostic), and patient clinical management process indicators but persistent gaps were also found in generic prescribing practices; compliance with essential medicine list best-practice standards; availability of drugs on the national essential medicine list; and affordability thereby warranting targeted policy interventions.

The demographic characteristics of our study population (male sex, 57.20%; rural domicile, 67.60%; socioeconomic status classes (IV – V), 61.80%) perfectly mirror the epidemiological profile of paediatric epilepsy in resource-constrained Indian settings. Srivastava *et al.* [16], in an epidemiological survey undertaken among 19,181 of rural children in India reported a prevalence of childhood epilepsy as 3.44 per 1,000 with a treatment gap of 45.45%, emphasizing that the tip of the iceberg (ie, people reaching tertiary care centre as opposed to total population) represents only the visible part of total disease burden on society. The comorbidity burden of 40.5% in our cohort—mainly developmental delay (22.0%) and cerebral palsy (8.1%)—is consistent with the results reported by Record *et al.* [17], who reported 56% of paediatric epilepsy patients to have neurodevelopmental comorbidities based on routine screening for other conditions backwards. Lower prevalence in the present study is likely due to under-detection by routine clinical evaluation and inclusion of a wider severity spectrum, including new patient presentations. These results highlight the importance of systematic neurodevelopmental screening in paediatric epilepsy clinics.

The monotherapy rate of 61.8% exceeds the WHO benchmark of>60% and is in line with a study by Khoshdel *et al.* who found similar monotherapy rates for their paediatric tertiary care cohort in Bangalore [10]. The preference for monotherapy is consistent with current evidence showing seizure freedom in>50% of new-onset cases who received single-agent therapy and minimises the pharmacokinetic complexities related to drug interactions in children with developing hepatic and renal function10. The mean of 1.43 drugs per encounter remained well below the WHO threshold (<2.0), reflecting judicious prescribing behaviour. Nevertheless, the fact that 38.2% of patients needed polytherapy highlights the intractable nature of a significant proportion of this population with paediatric epilepsy. Cho *et al.* Another 12-year longitudinal study involving 5593 patients with paediatric epilepsy from Korea had also reported an increasing trend in the use of polytherapy with increasing disease duration and age [18]. Kaur *et al.* In a cross-sectional study on antiepileptic drug prescribing trends in children, it was also reported that polytherapy was predominantly employed in patients with longer disease duration and poor seizure control [21].

Sodium valproate was the ASMs that were prescribed most frequently (27.4%), confirming its role as a well-established broad-spectrum first-line agent. Balagura *et al.* [11] describe valproate as the standard ASM for paediatric epilepsy pharmacotherapy, as it is effective in patients with generalised tonic–clonic, absence and myoclonic seizures. In our cohort, generalised tonic–clonic seizures were the most common presentation (39.3%), and idiopathic/genetic aetiology was implicated in 56.6% of cases where more than one diagnosis could be made clinically; such preferential selection for valproate was therefore appropriate on clinical grounds. However, resurgent concerns about the teratogenic potential and metabolic adverse effects of valproate must be balanced against risks in a risk–benefit calculation, especially for female adolescents of childbearing age [11].

Yildirim *et al.* In an open-label study, Levetiracetam monotherapy was shown to achieve greater than 50% seizure reduction in over 85% of paediatric patients, with retention rates of 81% at 6 mo and a low discontinuation rate (2.5%) due to adverse events [12]. In our study, the highest rate of appropriate dosing was observed with levetiracetam (93.8%), likely due to prescribers' familiarity with its linear pharmacokinetics and its large therapeutic window. The fact that "traditional" ASMs still accounted for 57.3% of all prescriptions reflects a transition period in prescription practices at Indian hospitals, as formulary restrictions, cost considerations, and prescribers' comfort with established agents shape drug selection. Das *et al.* In their review of antiepileptic drug adverse reactions within a paediatric tertiary care centre [22] similarly found that older-generation ASMs predominated and emphasized the need to monitor for adverse effects during this transitional prescribing period.

Analysis of the WHO/INRUD indicators suggested that, though many process indicators (consultation time, dispensing time, injection avoidance, prescription error rates) were generally satisfactory, there was a major gap in outcome-oriented quality indicators, especially in generic prescribing and adherence to the essential medicine list. In addition, some of the WHO/INRUD benchmarks, including 100% generic prescribing and 100% NLEM adherence, are ideals of aspirational targets rather than rigorously evidence-based thresholds. Aiming for 100% generic prescribing is less achievable in practice due to patient preference, specific clinical indications requiring branded products (e. g., NTIDs and bioequivalence issues), or EMLs that have not kept pace with current clinical practice [23]. At 73.0%, the rate of generic prescribing was below the WHO ideal of 100% but still comparable to national figures. In a WHO/INRUD-based assessment at a tertiary care facility in Pune, Magar *et al.* reported near-total generic prescribing and high adherence to the NLEM-both significantly higher than our current results [13]. This variation is probably a function of institutional formulary policies, rather than clinical providence. Jhaj *et al.* reported the largest ICMR multicentric analysis to date across 13 Indian tertiary institutes and found that a substantial portion of overall prescriptions (~55%) contained one or more non-NLEM drugs [14], attributing this to the increasing use of newer ASMs that are yet to be included in national formularies. The overall appropriateness of dosing (89.5%) exceeds the WHO target of>85%, and this is a reassuring finding. The conservatism in dosing, although justifiable, underscores the need for a systematic approach to dose optimisation, with subsequent TDM utilised to confirm adequate therapeutic exposure. However, the assessment was based solely on prescribed mg/kg/day doses rather than the BNF for Children reference ranges and did not advise therapeutic drug level monitoring for all patients. Czornyj *et al.* [15] studied more than 21,000 plasma ASM levels in a paediatric patient population and noted that over 70% of phenytoin prescriptions were associated with subtherapeutic concentrations relative to the prescribed dose when deemed appropriate. This discrepancy highlights the inadequacy of dose-based assessment alone and emphasises the significance of the 76.3% TDM rate achieved at our centre, which surpassed the WHO goal (>70%). These low appropriateness rates for phenobarbitone (81.8%) and topiramate (83.3%) highlight the need for directed prescriber education as these agents have narrower therapeutic indices in children. The affordability indicator was far less than the WHO target of>80% at 72.8% close to Singh *et al.* [22, 19], who show that many ASMs carry an overbearing economic burden, sometimes amounting to a month's wages for low-income workers in Punjab.

Strengths and limitations

This study has several strengths. This prospective design allowed for real-time capture of prescribing decisions, minimising the documentation bias associated with retrospective analyses. The global WHO/INRUD framework, comprising 21 indicators across four domains, enabled standardised, internationally comparable measures of quality. The drug-level dosing appropriateness analysis provided greater granularity than aggregate prescribing indicators. However, several limitations need to be noted. First, the single-centre design at a tertiary care hospital limits generalisability to private institutions and primary care settings. Second, the observed sample of 173 patients was smaller than previously calculated target sample of size 228 in reflection of 'real world' patient flow during the study period; nonetheless a precision rate of 7.5% at the level of confidence 95% remains satisfactory for descriptive observational studies, and consecutive sampling further improves representativeness towards the centre's routine working population during the study period. Third, the appropriateness of dosing was evaluated using prescribed mg/kg/day doses rather than measured plasma drug levels, which may include a considerable overestimation of actual pharmacological adequacy. Fourth, the study period was 7 mo, and it was not possible to evaluate seasonal variation or long-term treatment adjustment. Fourthly, the descriptive nature of this design

also precluded multivariate modelling to identify predictors of rational prescribing. Lastly, as seizure-outcome data are not linked to prescribing individuals, it is difficult to relate prescribing quality indicators to clinical efficacy.

Conclusion

This prospective observational study involves a review of 173 children attending a tertiary care centre in South India with epilepsy, which has highlighted the existing practice and several process indicators – monotherapy (61.8%), dosing (89.5%), diagnostic documentation (98.8%), TDM (76.3%), knowledge, and patient care. The mainstay of treatment continued to be sodium valproate (27.4%), whereas levetiracetam (19.4%) has become the chosen newer-generation agent.

Some clinically significant shortfalls remain across three policy-amenable domains: generic prescribing (73.0%) and essential medicines list adherence (66.1%) both continue to fall below WHO ideals; availability of key drugs (68.8%) illustrates vulnerabilities of supply chains; and the affordability gap (72.8% vs>80% target) underscores economic burden on families in lower socioeconomic strata. With a comorbidity burden of 40.5%, this further highlights the need for integrated neurodevelopmental care pathways. Prospective multicentre studies with larger sample sizes and linked seizure-outcome data are required to determine whether enhancements in prescribing indicators lead to demonstrable improvements in seizure control.

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Authors Contributions

Selvakumar A: Conceptualisation, data collection, data analysis and interpretation, drafting of the manuscript. Venkateswaramurthy N: Study design, critical revision of the manuscript for important intellectual content, and final approval of the version to be published.

Conflict of Interests

The authors declare no conflict of interest

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