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DRUG UTILIZATION PATTERN OF ANTIEPILEPTIC DRUGS IN TERTIARY CARE HOSPITAL

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ABSTRACT

Introduction: Drug utilization pattern is useful in the evaluation of the standards of therapy for people suffering with epilepsy and seizures. Drug utilization statistics are an important tool with which we can evaluate the quality of prescribing in a defined setting. Drug utilization pattern can increase understanding the rational drug use in seizures and its outcomes. **Aim:** To study the drug utilization pattern of antiepileptic drugs in a tertiary care hospital. **Methodology:** A prospective observational study was conducted for duration of six months in general medicine and pediatric wards of Gandhi hospital. During study period all anti-epileptic cases were collected on regular basis and these cases were analyzed for following results. **Results:** Age wise distribution shows 2-12 were more prevalent (P value –<0.01), males were more affected. Atypical febrile seizures were found to be highest in infants (P value- < 0.01), in Children GTCS 39.53% (n=17) was found to be highest, in adolescents GTCS, Unclassified seizures, Complex partial seizures, Status epilepticus, Atypical febrile seizures were distributed equally, in adults GTCS was found to be highest (P value- < 0.05). Causes for different type of seizures found that, space occupying lesions were significant cause for GTCS (P value < 0.01) and Infectious causes were significant for Unclassified seizures (P value- < 0.0001), Status epilepticus (P value- < 0.05), Atypical febrile seizures (P value- < 0.05), Simple febrile seizures (P value- < 0.05). Idiopathic cause is significant (P value- < 0.05) for Typical febrile seizures. Simple partial seizures were mostly caused due to Circulatory disturbances (P value- < 0.05). Dual therapy was most frequently used in Atypical febrile seizures, Complex partial seizures, Simple febrile seizures, simple partial seizures and monotherapy was used in GTCS, Unclassified seizures, Status epilepticus. Phenytoin was most commonly used drug in

all types of therapy. **Conclusion:** Utilization pattern of anti-epileptic drugs depends on age group, cause, type of seizure and choice of physician. Dual therapy was frequently used treatment option followed by monotherapy and Phenytoin was most common drug prescribed in all types of therapy.

KEYWORDS: antiepileptic drugs, choice of therapy, distribution of seizures, type of therapy, type of seizures.

INTRODUCTION

Drug utilization pattern

Drug utilization pattern is defined as the marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences.[1] In different social environments, antiepileptic drug (AED) utilization pattern is useful in the evaluation of the standards of therapy for people suffering with epilepsy[2] and seizures. Drug utilization statistics are an important tool with which we can evaluate the quality of prescribing in a defined setting.[3] Drug utilization pattern, can increase understanding the rational drug use in seizures and its outcomes.[4] Appropriate drug utilization studies are important tools to evaluate whether drugs are properly utilized in terms of efficacy, safety, convenience and economic aspects at all levels in the chain of drug use.[5] Drug utilization studies began in the early 1960s, and its importance has increased since then due to increase in marketing of new drugs, wide variation in drug prescribing pattern and consumption, growing concern about delayed adverse effects and cost of drugs. Purpose of the study is to investigate the use of AEDs in epilepsy and seizures, changes in prescription patterns, combination of drugs, and ADR profile of AEDs in a tertiary care hospital.[6]

Amongst the various factors affecting anti-epileptic drug (AED) usage, the major determinants are type of epilepsy, age and gender of patient, side effect profile and availability of medicines, affordability of the patient and preference of the treating physician as well as the practice setting.[7,8] During the assessment phase, it is critical to establish an accurate diagnosis of the seizure type and classification. The diagnosis of epilepsy is essentially clinical, based on an eyewitness account of the seizure.[9] The fundamental principle of managing epilepsy simply involves making an accurate diagnosis and choosing the most effective antiepileptic drug (AED) for the seizure type. Also it entails an effort on the part of physicians to first try out monotherapy regimes, exhausting possibilities and then only using polytherapy. The ultimate goal of antiepileptic therapy should be, to achieve a

seizure free state. A large number of antiepileptic drugs (AEDs) are available for the treatment of epilepsy.

Anti-epileptic drugs (AEDs) control abnormal neuronal activity by elevating the threshold of neurons to electrical or chemical stimuli or by limiting the propagation of the seizure discharge from its origin.[10]

Usage of AEDs differs in different geographical regions, depending partly on economic, development and drug availability.[11] Hence we have made an attempt to study the utilization pattern of anti-epileptic drugs (AEDs) in different types of epilepsy and seizures according to age, gender and type of seizures.

MATERIALS AND METHODS

Study site: In-patient Departments of General Medicine and Paediatrics in Gandhi hospital, Secunderabad.

Study design: This was a hospital based prospective observational study conducted on patients who are on AEDs of in-patient department to review the current prescribing pattern of antiepileptic drugs in patients with epilepsy and seizures.

Study duration: 6 months

Study period: August 2015 to January 2016.

Inclusion criteria

- Patients with all types of seizures and epilepsy.
- Patients of all age groups and both genders.
- Patients visiting in-patient department of both pediatrics and general medicine.

Exclusion criteria

- Pregnant women who are taking AEDs.
- Patients who are in comatose conditions.

Study procedure

The study was conducted in a Tertiary Care Hospital to see the drug utilisation pattern of anti-epileptic drugs. A Prospective observational study was conducted, it includes following:

- Participated in ward rounds on regular basis.

- All epileptic cases were identified according to inclusion criteria and documented them in structured documentation form.
- Collected cases were analysed and drug use pattern of anti-epileptic drugs were checked for different types of epilepsy in all age groups and both genders.
- Final report was prepared and submitted.

Statistical approach

Interpreted data was statistically analyzed by using "Graph pad prism" version 6.07 software. One sample t- test was performed to analyze various parameters to obtain statistical significance for each parameter.

Statistical significance

P value - <0.01, <0.05, <0.001, <0.0001.

RESULTS AND DISCUSSION

Total no. of cases were 120 and were analyzed for the following results:

Table I: Age wise distribution

Age groups	No. of cases (n)	Percentage (%)
Neonates(birth-1m)	2	1.67%
Infants(>1m-2yr)	32	26.67%
Children (>2-12yrs)	48	40.00%
Adolescents(>12-<18)	6	5.00%
Adults (>18)	32	26.67%
Total	120	100.00%

Total no. of patients were distributed according to age groups. More prevalent age group was between 2-12 (children) followed by infants and adults and it was statistically significant (P value -<0.01). These results were supported by a study conducted by Sebastian J et al., (2013).

Table II: Gender wise distribution

Gender	No. of cases (n)	Percentage (%)
Male	66	55%
Female	54	45.00%
Total	120	100.00%

Total no. of patients were distributed according to gender. Males were more prevalent.Our study in this case matches with a previous study conducted by Pathak S et al., (2013), Murthy VN et al., (2012) Mazhar Fet al., (2015), Habib Met al., (2013), Badwaik RT et al., (2015), Ahsan-Haroon et al.,(2012) George J et al., (2015), Sebastian J, Adepu R et al., (2013), Jena M et al., (2014).

Table III: Distribution based on etiologic factors

Cause	No. of cases (n)	Percentage (%)
Infectious	36	30.00%
Idiopathic	22	18.33%
Space occupying lesions	17	14.17%
Break through	12	10.00%
Congenital	10	8.33%
Circulatory disturbances	9	7.50%
Genetic	6	5.00%
Toxic	4	3.33%
Metabolic	2	1.67%
Trauma	2	1.67%
Total	120	100.00%

Total no. of patients were distributed according to causes. Among all the causes infectious cause was mostly observed and it was statistically insignificant (P value ->0.10).

1. Type of seizures

Table IV: Distribution based on Type of seizures

Type of seizures	No. of cases (n)	Percentage (%)
GTCS	34	28.33%
Unclassified	22	18.33%
Status epilepticus	19	15.83%
Atypical febrile seizures	11	9.17%
Complex partial seizures	11	9.17%
Simple febrile seizures	8	6.675%
Typical febrile seizures	4	3.33%
Simple partial seizures	4	3.33%
Alcohol withdrawal seizures	4	3.33%
Unprovoked seizures	2	1.67%
Atonic seizures	1	0.83%
Total	120	100.00%

Total no. of patients were distributed according to type of Seizures. GTCS was mostly occurred type of seizure followed by unclassified seizures and it was statistically significant (P value -<0.01). Our study matches with the previous study conducted by Munoli S et al.,

(2013), Ya'uet al., (2013), Murthy VN et al., (2012), Hanssenset al., (2002), Pal A et al., (2011), RisheW et al., (2015).

2. Type of therapy

Table V: Distribution based on Type of therapy

Type of therapy	No. of cases (n)	Percentage (%)
Mono	49	40.00%
Combination:		
Dual	56	46.66%
Triple	11	10.00%
Quadruple	2	1.67%
Pentavalent	2	1.67%
Total	120	100.00%

Total no. of patients were distributed according to Type of therapy. Dual therapy was mostly prescribed type of therapy followed by monotherapy, this matches with the study by Jena M et al., (2014).

Table VI: Distribution of drugs based on Monotherapy

Drugs given	No. of cases (n)	Percentage (%)
Phenytoin	27	56.24%
Calobazam	8	16.67%
Sodium valproate	5	10.42%
Midazolam	2	4.17%
Carbamazepine	2	4.17%
Chlordiazepoxide	2	4.17%
Diazepam	1	2.08%
Levetiracetam	1	2.08%
Total	48	100.00%

Total no. of patients were distributed according to type of drug prescribed. Mostly prescribed drug was phenytoin and it was statistically significant (P value -<0.05). This matches with the previous studies conducted by Badwaik RT et al., (2015), Naithani M et al (2012), Shih- Hui LIM et al., (1997).

Table VII: Distribution of drugs based on Dual therapy

Drugs given	No. of cases (n)	Percentage (%)
Phenytoin + Midazolam	16	28.57%
Clobazam + Midazolam	10	17.89%
Carbamazepine+ Midazolam	5	8.93%
Phenytoin + Clobazam	5	8.93%
Phenytoin+ Sodium valproate	4	7.14%
Midazolam+ Sodium valproate	4	7.14%

Phenytoin + Carbamazepine	2	3.57%
Phenytoin+ Levetiracetam	2	3.57%
Chlordiazepoxide+ Clonazepam	1	1.79%
Phenobarbitone+ Midazolam	1	1.79%
Midazolam+ Levetiracetam	1	1.79%
Phenytoin + Chlordiazepoxide	1	1.79%
Phenytoin + Diazepam	1	1.79%
Phenobarbitone + Clobazam	1	1.79%
Sodium valproate+ Levetiracetam	1	1.79%
Sodium valproate + Clobazam	1	1.79%
Total	56	100.00%

Total no. of patients were distributed according to combination of two drugs prescribed Mostly prescribed dual combination was Phenytoin + Midazolam and it was statistically significant (P value -<0.01).

Table VIII: Distribution of drugs based on triple therapy

Drugs given	No. of cases (n)	Percentage (%)
Phenytoin + Sodium valproate + Midazolam	2	16.67%
Phenytoin + Midazolam + Clobazam	2	16.67%
Phenytoin+ Midazolam+ Carbamazepine	2	16.67%
Phenytoin+ Sodium valproate+ Clobazam	1	8.33%
Phenytoin + Sodium valproate + Clobazam	1	8.33%
Midazolam + Phenobarbitone + Levetiracetam	1	8.33%
Phenytoin+ Clobazam+ Levetiracetam	1	8.33%
Sodium valproate + Levetiracetam + Topiramate	1	8.33%
Clonazepam+ Clobazam+ Sodium valproate	1	8.33%
Total	12	100.00%

Total no. of patients were distributed according to combination of three drugs prescribed Mostly prescribed triple combination was Phenytoin+ Sodium Valproate + Midazolam and it was statistically significant (P value -<0.0001).

Phenytoin was most common drug prescribed in all types of therapy, which matches with the previous studies conducted by A. Ramyaet al., (2015), Deepalakshmi Met al., (2013), Naithani M et al., (2012).

3. Age versus type of seizures

Total no. of patients were distributed according to type of seizures in different age groups. In Neonates both Atypical febrile seizures and Unclassified seizures were distributed equally.

Table IX: Distribution of different types of seizures in infants

Type of seizure	No. of cases(n)	Percentage (%)
Atypical febrile seizures	9	32.14%
GTCS	6	21.42%
Status Epilepticus	5	17.86%
Typical febrile seizures	4	14.29%
Simple febrile seizures	4	14.29%
Total	28	100.00%

Total no. of patients were distributed according to type of seizures in different age groups. Atypical febrile seizures were found to be highest in Infants and it was statistically significant (P value- < 0.01).

Table X: Distribution of different type of seizures in children

Type of seizure	No. of cases(n)	Percentage (%)
GTCS	17	39.53%
Unclassified seizures	9	20.93%
Complex partial seizures	8	18.60%
Status Epilepticus	6	13.95%
Simple Febrile seizures	2	4.65%
Simple Partial seizures	1	2.33%
Total	43	100.00%

Total no. of patients were distributed according to type of seizures in different age groups. GTCS was found to be highest in Children and it was statistically insignificant (P value- > 0.01).

In adolescents GTCS, Unclassified seizures, Complex partial seizures, Status epilepticus, Atypical febrile seizures were equally distributed.

Table XI: Distribution of different type of seizures in adults:

Type of seizure	No. of cases(n)	Percentage (%)
GTCS	10	31.25%
Unclassified seizures	7	21.87%
Complex partial seizures	1	3.13%
Status Epilepticus	7	21.87%
Simple Partial seizures	3	9.38%
Alcohol withdrawal seizures	4	12.50%
Total	32	100.00%

Total no. of patients were distributed according to type of seizures in different age groups. GTCS was found to be highest in adults and it was statistically significant (P value- < 0.05).

4. Cause versus type of seizure

Table XII: Distribution of different type of causes in GTCS

Causes	GTCS	
	No. of cases (n)	Percentage (%)
Infectious	6	17.67%
Idiopathic	5	14..70%
Space occupying lesions	7	20.58%
Break through	7	20.58%
Congenital	6	17.67%
Circulatory disturbances	2	5.88%
Genetic	1	2.94%
Total	34	100.00%

Total no. of patients were distributed according to causes in different type of seizures. Space occupying lesions and break through were found to be highest cause in GTCS and it was statistically significant (P value- < 0.0001).

Table XIII: Distribution of different type of causes in Unclassified seizures

Causes	Unclassified	
	No. of cases (n)	Percentage (%)
Infectious	4	18.18%
Idiopathic	3	13.63%
Space occupying lesions	2	9.09%
Break through	3	13.63%
Congenital	3	13.63%
Circulatory disturbances	3	13.63%
Metabolic	2	9.09%
Trauma	2	9.09%
Total	22	100.00%

Total no. of patients were distributed according to causes in different type of seizures. Infectious cause was found to be highest in Unclassified seizures and it was statistically significant (P value- < 0.0001).

Table XIV: Distribution of different type of causes in Status epilepticus

Causes	Status epilepticus	
	No. of cases (n)	Percentage (%)
Infectious	10	52.63%
Idiopathic	5	26.31%
Space occupying lesions	1	5.26%
Break through	2	10.52%
Circulatory disturbances	1	5.26%
Total	19	100.00%

Total no. of patients were distributed according to causes in different type of seizures Infectious cause was found to be highest in Status epilepticus and it was statistically significant (P value- < 0.05).

Table XV: Distribution of different type of causes in Atypical febrile seizures

Causes	Atypical febrile seizures	
	No. of cases (n)	Percentage (%)
Infectious	5	45.45%
Idiopathic	2	18.18%
Congenital	1	9.09%
Genetic	3	27.27%
Total	11	100.00%

Total no. of patients were distributed according to causes in different type of seizures infectious cause was found to be highest in Atypical febrile seizures and it was statistically significant (P value- < 0.05).

Table XVI: Distribution of different type of causes in Complex partial seizures

Causes	Complex partial seizures	
	No. of cases (n)	Percentage (%)
Infectious	3	27.27%
Idiopathic	1	9.09%
Space occupying lesions	6	54.54%
Genetic	1	9.09%
Total	11	100.00%

Total no. of patients were distributed according to causes in different type of seizures Space occupying lesions were found to be highest in Complex partial seizures and it was statistically significant (P value- < 0.01).

Table XVII: Distribution of different type of causes in Simple febrile seizures

Causes	Simple febrile seizures	
	No. of cases (n)	Percentage (%)
Infectious	6	75.00%
Idiopathic	1	12.50%
Genetic	1	12.50%
Total	8	100.00%

Total no. of patients were distributed according to causes in different type of seizures infectious cause was found to be highest in Simple febrile seizures and it was statistically significant (P value- < 0.05).

Table XVIII: Distribution of different type of causes in Typical febrile seizures

Causes	Typical febrile seizures	
	No. of cases (n)	Percentage (%)
Infectious	1	25.00%
Idiopathic	3	75.00%
Total	4	100.00%

Total no. of patients were distributed according to causes in different type of seizures Idiopathic cause was found to be highest in Typical febrile seizures and it was statistically significant (P value- < 0.05).

Table XIX: Distribution of different type of causes in Simple partial seizure:

Causes	Simple partial seizures	
	No. of cases (n)	Percentage (%)
Space occupying lesions	2	40.00%
Circulatory disturbances	3	60.00%
Total	5	100.00%

Total no. of patients were distributed according to causes in different type of seizures Circulatory disturbances were found to be highest in Simple partial seizures and it was statistically significant (P value- < 0.05).

In alcohol withdrawal seizures only cause found was toxicity. In unprovoked seizures both Infectious and Idiopathic causes were found to be distributed equally. Only idiopathic cause was seen in atonic seizures.

5. Type of seizure versus type of therapy

Table XX: Type of therapy in GTCS

GTCS	Monotherapy		Dual therapy		Triple therapy	
	n	%	n	%	n	%
	15	48.38%	13	41.90%	3	9.67%

Table XXI: Monotherapy in GTCS

Drug	No. of cases(n)	Percentage (%)
Phenytoin	8	53.33%
Clobazam	4	26.67%
Diazepam	1	6.67%
Sodium Valproate	1	6.67%
Carbamazepine	1	6.67%
Total	15	100.00%

Total no. of patients were distributed according to type of therapy in different type of seizures. Monotherapy was found to be highest in GTCS and Phenytoin was mostly prescribed drug in monotherapy and it was statistically significant (P value- < 0.0001).

Table XXII: Type of therapy in Unclassified seizures

Unclassified	Monotherapy		Dual therapy		Pentavalent therapy	
	n	%	n	%	n	%
	12	54.54%	9	40.90%	1	4.54%

Table XXIII: Monotherapy in Unclassified

Drug	No. of cases(n)	Percentage (%)
Phenytoin	9	75.00%
Carbamazepine	1	8.33%
Sodium Valproate	1	8.33%
Levetiracetam	1	8.33%
Total	12	100.00%

Total no. of patients were distributed according to type of therapy in different type of seizures. Monotherapy was found to be highest in Unclassified seizures and Phenytoin was mostly prescribed drug in monotherapy and it was statistically significant (P value- < 0.01).

Table XXIV: Type of therapy in status epilepticus

Status Epilepticus	Monotherapy		Dual therapy		Triple therapy	
	n	%	n	%	n	%
	10	52.63%	7	36.84%	2	10.52%

Table XXV: Monotherapy in status epilepticus

Drug	No. of cases(n)	Percentage (%)
Phenytoin	7	70.00%
Sodium Valproate	1	10.00%
Midazolam	1	10.00%
Clobazam	1	10.00%
Total	10	100.00%

Total no. of patients were distributed according to type of therapy in different type of seizures. Monotherapy was found to be highest in Status epilepticus and Phenytoin was mostly prescribed drug in monotherapy and it was statistically significant (P value- < 0.05).

Table XXVI: Type of therapy in Atypical Febrile

Atypical Febrile	Monotherapy		Dual therapy		Triple therapy	
	n	%	n	%	n	%
	1	9.09%	7	63.63%	3	27.27%

Table XXVII: Dual therapy in Atypical Febrile

Drug	No. of cases(n)	Percentage (%)
Clobazam+Midazolam	4	57.14%
Phenytoin+Midazolam	2	28.57%
Sodium valproate+Midazolam	1	14.29%
Total	7	100.00%

Total no. of patients were distributed according to type of therapy in different type of seizures. Dual therapy was found to be highest in Atypical febrile seizures and Clobazam + Midazolam was mostly prescribed drug combination in dual therapy and it was statistically significant (P value- < 0.0001).

Table XXVIII: Type of therapy in Complex Partial seizures

Complex Partial	Monotherapy		Dual therapy		Triple therapy	
	n	%	n	%	n	%
	3	27.27%	6	54.54%	2	18.18%

Table XXIX: Dual therapy in Complex Partial seizures

Drug	No. of cases(n)	Percentage (%)
Phenobarbitone+Carbamazepine	2	33.33%
Carbamazepine+Midazolam	4	66.67%
Total	6	100.00%

Total no. of patients were distributed according to type of therapy in different type of seizures. Dual therapy was found to be highest in Complex partial seizures and Carbamazepine + Midazolam was mostly prescribed drug combination in dual therapy and it was statistically significant (P value- < 0.01).

Table XXX: Type of therapy in Simple Febrile seizures

Simple Febrile	Monotherapy		Dual therapy		Triple therapy	
	n	%	n	%	n	%
	3	37.50%	5	62.50%	0	0.00%

Table XXXI: Dual therapy in Simple Febrile seizures

Drug	No. of cases(n)	Percentage (%)
Phenytoin+Midazolam	1	20.00%
Clobazam+Midazolam	4	80.00%
Total	5	100.00%

Total no. of patients were distributed according to type of therapy in different type of seizures. Dual therapy was found to be highest in Simple febrile seizures and Clobazam +

Midazolam was mostly prescribed drug combination in dual therapy and it was statistically significant (P value- < 0.01).

Dual therapy was highest in simple partial seizures. In Alcoholic withdrawal seizures and typical febrile seizures, both monotherapy 50% (n=2) and dual therapy 50% (n=2) was equally seen. In Unprovoked seizures (n=2) and Atonic seizures (n=1) only dual therapy was prescribed.

CONCLUSION

Our study in contrast with other studies elaborates the drug usage pattern according to different parameters like age, gender and cause of seizures. Age wise distribution shows, children between 2-12 yrs. were more prevalent. Gender wise distribution shows males were more affected. Out of all the epileptic causes infectious cause was highest. Among all the types of seizures, Seizure disorder was more prominent. Dual therapy was frequently used. Phenytoin was most common drug prescribed in all types of therapy. Thus dose monitoring of AEDs and selection of combination is vital in control of seizures as choice of drug used and combination f drugs used changes according to age and cause of seizures.

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