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Original Article *Özgün Araştırma*

COMPARISON OF CARBAMAZEPINE AND LEVETIRACETAM MONOTHERAPY IN CHILDHOOD ROLANDIC EPILEPSY

Çocukluk Çağı Rolandik Epilepsi Hastalarında Karbamazepin ve Levetirasetam Monoterapilerinin Karşılaştırılması

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ABSTRACT

Objective: Rolandic epilepsy (RE) is the most common benign focal epilepsy of childhood. While carbamazepine (CBZ) has been widely used in treatment, levetiracetam (LEV) has become one of the first-line options in recent years due to its efficacy and good tolerability. The aim of this study was to compare CBZ and LEV monotherapies in the treatment of RE.

Material and Methods: Thirty patients with RE (15 treated with CBZ and 15 with LEV) who were followed at Sütçü İmam University during the last three-year period were retrospectively analyzed. Demographic and clinical characteristics, including age, sex, age at seizure onset, seizure type, and seizure frequency, were evaluated. Changes in seizure frequency after treatment, treatment-related adverse effects, and electroencephalographic (EEG) response were systematically assessed.

Results: Of the 30 patients, 20 (66.7%) were male and 10 (33.3%) were female. Twelve patients (80%) in the CBZ group and eight patients (53.3%) in the LEV group were male. The median age at diagnosis was 8.1 years (6.8-8.9), and the median age at treatment initiation was 8.1 years (7.0-8.8). There were no significant differences between the groups regarding sex distribution, age at diagnosis, or age at treatment initiation. No significant difference was found between the two treatment groups in terms of reduction in seizure frequency after treatment. EEG normalization during follow-up was observed in 9 patients (31%), with no significant difference between the groups in EEG normalization frequency or time to normalization. Treatment-related adverse effects were observed in 10 patients (33.3%), with no significant difference between the CBZ and LEV groups.

Conclusion: Although no statistically significant differences were found between CBZ and LEV in terms of seizure control, adverse effects, and EEG outcomes, our findings support the use of LEV as an effective monotherapy option in the treatment of childhood RE.

Keywords: *Rolandic epilepsy, carbamazepine, levetiracetam*

ÖZ

Amaç: Rolandik epilepsi (RE), çocukluk çağının en sık görülen benign fokal epilepsisidir. Tedavide karbamazepin (CBZ) yaygın kullanılan bir antiepileptikken, levetirasetam (LEV) da son yıllarda etkinliği ve iyi tolere edilebilirliği sebebiyle ilk tercihlerden biri olarak yer almıştır. Çalışmamızın amacı RE tedavisinde CBZ ve LEV monoterapilerinin karşılaştırılmasıdır.

Gereç ve Yöntemler: Son üç yılda Sütçü İman Üniversitesinde takip edilen 30 RE hastası (15 CBZ, 15 LEV) retrospektif olarak analiz edildi. Yaş, cinsiyet, nöbet başlangıç yaşı, nöbet tipi ve nöbet sıklığı gibi demografik ve klinik özellikler değerlendirildi. Tedavi sonrası nöbet sıklığındaki değişimler ve yan etkiler, tedaviye elektroensefalografi (EEG) yanıtı sistematik olarak incelendi.

Bulgular: Çalışmamızdaki 30 hastanın 20'si erkek (%66,7), 10'u kızdı (%33,3). CBZ grubunun 12'si (%80) erkek, LEV grubunun 8'i (%53,3) erkekti. Grubun tanı yaşı 8,1 (6,8-8,9) yıl [median (%25-75)], tedavi başlama yaşı 8,1 (7,0-8,8) yıldı. Gruplar arasında cinsiyet, tanı ve tedavi başlanma yaşı açısından fark yoktu (sırayla p=0,245; 0,068; 0,085). Tedavi sonrası nöbet sıklığı azalmasında iki ilaç grubu arasında anlamlı fark bulunmadı. Tüm hastaların 9'unda (%31) tedavi süresinde EEG'de normale dönme olduğu görüldü. Gruplar arasında EEG'de düzelme sıklıkları açısından fark yoktu. EEG'nin normale dönme süresi CBZ grubunda 34 (16-36) ay, LEV grubunda 14 (7-33) aydı. EEG düzelme süresi karşılaştırmasında gruplar arasında anlamlı fark görülmedi. Tüm grupta 10 hastada (%33,3) tedaviye bağlı yan etki geliştiği görüldü. Yan etki sıklığı CBZ grubunda 3 (%20), LEV grubunda 7 (%46,7) idi ve aralarında anlamlı fark yoktu (p=0,245).

Sonuç: RE tedavisinde nöbet kontrolü, yan etkiler ve EEG bulguları açısından CBZ ve LEV arasında istatistiksel olarak anlamlı bir fark olmamasına karşın, çalışmamız LEV'in etkili bir monoterapötik ajan olarak kullanımını desteklemektedir.

Anahtar Kelimeler: *Rolandik epilepsi, karbamazepin, levetirasetam*

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INTRODUCTION

Rolandic epilepsy (RE) is a benign childhood epilepsy, accounting for 8-25% of pediatric epilepsy cases.[1] It affects about 15% of children with epilepsy between ages 1 and 15, with seizures typically starting between ages 7 and 10.[2] The condition is more common in boys.[3] Genetic factors contribute to RE, with 25% of patients having a family history of febrile convulsions or epilepsy.[4] It follows an autosomal dominant inheritance pattern, linked to chromosomes 11q13 and 15q14.[5,6] Mutations in *RBFOX1*, *RBFOX3*, *DEPDC5*, *GABRG2* genes, and 16p11.2 duplications affect 1.5-2.0% of patients.[7,8]

A key feature of RE is high-voltage centrotemporal sharp waves on electroencephalography (EEG), especially during sleep.[9] Seizures usually involve tonic-clonic facial contractions and focal paresthesias during sleep, though generalized seizures may occur. RE generally resolves in adolescence and is considered benign.[10]

While RE generally has a favorable outcome, it may still lead to cognitive deficits, particularly in auditory-verbal memory, auditory perception, reading, spelling, grammar, visuomotor integration, and attention.[11,12] Behavioral and neuropsychological problems may also arise during active disease periods.[13]

Carbamazepine (CBZ) is a common first-line treatment; however, levetiracetam (LEV), valproic acid, sulthiame, clonazepam, barbiturates, primidone, clobazam, and phenytoin have also shown efficacy.[14,15]

This study evaluated RE patients at the Pediatric Neurology Department of Kahramanmaraş Sütçü İmam University who received CBZ or LEV. By comparing their efficacy, we aimed to contribute to the existing national and international literature.

MATERIALS AND METHODS

This study was designed as a single-center retrospective observational study. This retrospective study included 30 patients diagnosed with RE who were followed at the Pediatric Neurology Department of Kahramanmaraş Sütçü İmam University Faculty of Medicine during the last three-year period. Patient data were retrospectively collected from outpatient clinic records and hospital discharge reports. The patients' EEG records were obtained from the hospital's EEG archive.

Rolandic epilepsy diagnosis was based on characteristic seizure features, including tonic, clonic, or tonic-clonic convulsions with somatosensory onset, starting in the face and often spreading unilaterally to the extremities, as well as affecting the pharyngeal and laryngeal muscles. Diagnosis also included the presence of spike or multispike waves originating from the middle temporal and centrotemporal regions on interictal EEG. Additionally, initial systemic and neurological examinations were normal.[16-18]

Patients diagnosed and regularly followed up at the Pediatric Neurology Department of Kahramanmaraş Sütçü İmam University during the last three-year period, who did not have a chronic disease that could cause seizures, had clinical and typical EEG findings meeting the RE diagnostic criteria, and were treated with only one of either CBZ or LEV and followed up for at least six months were included in the study. Patients with progressive neurological diseases, neurometabolic disorders, other causes of seizures, polytherapy or insufficient follow-up were excluded.

For this study, 30 patients were evaluated; demographic information (gender, current age, seizure onset age), clinical seizure profiles (type, frequency, and duration), family background, and any prior epilepsy or febrile seizure history were documented. Of these, 15 patients received CBZ**,** and the remaining 15 received LEV. EEG findings at diagnosis, physical examination, and cranial magnetic resonance imaging results were also recorded. EEG was performed at baseline and 3- month intervals during follow-up. EEG normalization was defined as the absence of epileptiform activity on follow-up EEG recordings. The presence or absence of EEG normalization during the follow-up period was recorded. Time to EEG normalization was evaluated among patients who documented EEG normalization. The duration and frequency of seizures observed after treatment, as well as any side effects, were determined from patient files during follow-up. In terms of clinical response, patients who remained seizure-free for at least 6 months were defined as seizure-free, while those who had a 50% or greater reduction in monthly seizure frequency were considered responders. EEG response to treatment was assessed through improvements observed in EEGs taken every 3 months. Adverse effects and drug tolerability in both groups were assessed based on clinical follow-up records.

Statistical Analysis

First, the descriptive characteristics of the variables (mean, median, frequency, and percentage) were calculated. The normality of numerical variables was assessed. For numerical variables that did not follow a normal distribution, the Mann-Whitney U test was used for comparisons between two groups, and the Kruskal-Wallis test was used for comparisons among more than two groups. Categorical variables were compared using the chi-square test, while the McNemar test was used for the comparison of dependent categorical variables. All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 25. A p-value of <0.05 was considered statistically significant.

This retrospective study was approved by the Clinical Research Ethics Committee of Sütcü Imam University

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Faculty of Medicine (date: 19/10/2022, decision number: 01).

RESULTS

The study included 30 patients with RE who were treated with either CBZ or LEV. Of the 30 patients, 20 (66.7%) were male. There were no significant differences between CBZ and LEV groups regarding gender, age at diagnosis, age at first seizure, age at treatment initiation or follow-up duration (Table 1).

Table 1: Gender and age characteristics of patients

Characteristic	Total Group	CBZ Group	LEV Group	p-value
Gender*				0.245
Female	10 (33.3)	3 (20)	7 (46.7)	
Male	20 (66.7)	12 (80)	8 (53.3)	
Age at diagnosis ** (years)	8.1 (6.8-8.9)	7.8 (6.3-8.3)	8.3 (7.3-10.4)	0.068
Age at first seizure ** (years)	7.0 (5.2-8.3)	6.1 (4.8-8.1)	7.2 (6.1-10.3)	0.141
Age at treatment initiation ** (years)	8.1 (7.0-8.8)	7.9 (6.3-8.6)	8.6 (77.3-10.4)	0.085
Follow-up duration (months)	22 (16-35)	22 (17-36)	22 (12-35)	0.516

CBZ: Carbamazepine, LEV: Levetiracetam.
Data are presented as n (%) or median (25th-75th percentile), *number (percentage) **median (%25-75)

In the entire group, the median seizure duration before treatment was 75 (30-180) seconds, which decreased to 60 (36-120) seconds after treatment. In the entire cohort, median seizure duration significantly decreased after treatment (p=0.011). When CBZ and LEV groups were analyzed separately, no significant difference was observed between the groups regarding median seizure duration before and after treatment (p=0.102, p=0.058). When seizure frequencies during the last three months before treatment initiation and during the first three and first six months after treatment initiation were evaluated, a significant difference was observed between pre-treatment and post-treatment seizure frequencies both in the overall cohort and within the treatment groups. Although a marked reduction in seizure frequency was observed in the overall cohort after treatment initiation, there was no statistically significant difference between the LEV and CBZ groups regarding the magnitude of seizure frequency reduction observed before and after treatment. Seizure frequencies before and after treatment are summarized in Table 2.

Table 2: Seizure frequency before and after treatment

	Total Group	CBZ Group	LEV Group	p-value*
Seizure frequency in last 3 months before treatment (/month)	0.3 (0.3-0.7)	0.3 (0.3-0.7)	0.3 (0.3-0.7)	0.478
Seizure frequency in first 3 months after treatment (/month)	0 (0-0)	0 (0-0)	0 (0-0)	1,000
Seizure frequency in first 6 months after treatment (/month)	0 (0-0.2)	0 (0-0.2)	0 (0-0.2)	1,000
**Before-after p-value ** **	<0.001	<0.001	<0.001	

CBZ: Carbamazepine, LEV: Levetiracetam. Data are presented as median (25th-75th percentile). *Mann-Whitney U test.**Wilcoxon signed-rank test for before-after comparisons.

EEG normalization during the treatment period was observed in 9 patients (31%) overall. Among patients who achieved EEG normalization during follow-up, the median time to EEG normalization was 17 months (11-34) for the entire cohort, 34 months (16-36) in the CBZ group, and 14 months (7-33) in the LEV group. No statistically significant differences were observed between the groups regarding either the time to EEG normalization or the frequency of EEG improvement. Post-treatment EEG characteristics are presented in Table 3.

Table 3: EEG normalization and time to normalization after treatment

	Total Group	CBZ Group	LEV Group	p-value
EEG normalization after treatment				0.245
Yes, n, (%)	9 (31)	3 (20)	6 (42.9)	
No, n, (%)	20 (69)	12 (80)	8 (57.1)	
EEG normalization time (months)	17 (11-34)	34 (16-36)	14 (7-33)	0.154

EEG: Electroencephalography, CBZ: Carbamazepine, LEV: Levetiracetam. Data are presented as n (%) or median (25th-75th percentile).

In the evaluation of adverse effects, treatment-related adverse events were observed in 10 patients (33.3%) overall. Adverse effects occurred in 3 patients in the CBZ group and in 7 patients in the LEV group. The incidence of adverse effects was 20% in the CBZ group and 46.7% in the LEV group, with no statistically significant difference between the groups (p=0.245). When adverse effects were evaluated by treatment groups, no abnormalities were detected in biochemical or hematological parameters.

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Among all patients who experienced adverse effects, irritability was observed in 13.3%, somnolence in 10%, increased appetite and rash in 3.3% each, and decreased appetite in 10%. There was no significant difference between the groups regarding the distribution of adverse effect types according to treatment groups. Due to rash as an adverse effect, treatment was switched in one patient in the LEV group in the seventh month of therapy.

When clinical response criteria were evaluated during the first 6 months after treatment initiation, seizure freedom was achieved in 93.3% of all patients, while a ≥50% reduction in seizure frequency compared to the pre-treatment period was observed in 6.7%. No statistically significant difference was observed between the two treatment groups in terms of clinical response to treatment (Table 4).

Table 4: Clinical treatment response during the first six months

	Total Group	CBZ Group	LEV Group	p-value
First six months after treatment				0.483
Seizure-Free in first 6 months	28 (93.3%)	15 (100%)	13 (86.7%)	
≥50% reduction in seizure frequency	2 (6.7%)	0 (0%)	2 (13.3%)	

CBZ: Carbamazepine, LEV: Levetiracetam.Data are presented as n (%), Percentages are calculated within each treatment group.

DISCUSSION

The choice between LEV and CBZ in the treatment of RE is not limited solely to seizure control efficacy; it should be considered within a broader clinical framework that includes cost and accessibility, long-term cognitive outcomes, long-term adverse effect profile, and practical aspects such as dosing regimen and frequency of administration. CBZ has long been used, with well-established efficacy, and is considered a conventional first-line treatment option in many healthcare systems due to its relatively lower cost. However, its potential for drug-drug interactions, possible effects on cognitive functions, and long-term adverse event risk are factors that must be taken into account in clinical decision-making. In contrast, LEV has emerged as an important alternative, particularly in the pediatric population, owing to its favorable pharmacokinetic properties, minimal hepatic metabolism, and low potential for drug interactions.[19-22]

In this study, we evaluated the clinical efficacy, EEG outcomes and tolerability of CBZ and LEV in children with RE. Both CBZ and LEV were effective in reducing seizure frequency in children with RE. High rates of seizure freedom were observed during the first six months of treatment and no significant differences were found between the two treatment groups in terms of clinical response, EEG normalization or adverse effect profiles.

Several previous studies have reported similar findings. Ahadi et al. and Kanemura et al. also found a significant reduction in seizure frequency after treatment with both CBZ and LEV but did not observe a statistically significant difference between the two drugs.[19,20] Our results are in line with these studies, suggesting that both CBZ and LEV offer comparable efficacy in seizure control in RE.

In the study by Kanemura et al., 61 patients (68.5%) in the CBZ group and 30 patients (85.7%) in the LEV group were seizure-free during the first year of treatment, with both groups demonstrating a greater than 50% reduction in monthly seizure frequency.[20] Similarly, Ahadi et al. reported a significant decrease in seizure frequency from before to after treatment, but found no significant difference between the CBZ and LEV groups.[19] In our study, we observed a significant reduction in seizure frequency across the entire group, which is consistent with findings in the literature. However, no significant difference was found between LEV and CBZ when assessing seizure frequency before treatment and 3 and 6 months after treatment. This suggests that both drugs are effective in controlling seizures, but more extensive studies are needed.

In our study, EEG normalization appeared to occur earlier and more frequently in the LEV group compared to the CBZ group; however, this difference did not reach statistical significance. Similar trends toward earlier EEG improvement with LEV have been reported in previous studies.[20,21] Nevertheless, these findings should be interpreted with caution, as the lack of statistical significance in our cohort may be related to the limited sample size and short follow-up period. Therefore, while LEV may show a tendency toward earlier EEG normalization, larger prospective studies are needed to clarify its clinical relevance.

In a 2020 study in Iran by Ahadi et al., involving 94 patients with RE, one patient in the CBZ group and one in the LEV group experienced a loss of appetite severe enough to require a change in treatment. It was reported that no other side effects were observed, except for a temporary rash in 2 of the 47 patients in the CBZ group. [19] In a study conducted by Kanemura et al. in Japan in 2018 with 197 RE patients, only 2 patients in the LEV group experienced mild drowsiness that did not require a change in medication. [20]

In a study conducted by Xiao et al. in China in 2014 with 56 patients with RE, 9 patients receiving LEV treatment experienced dizziness and temporary drowsiness, irritability and mild hair loss in the first days

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of treatment. Apart from these, no serious side effects that would cause a change in treatment were reported.[21] In their review of recent studies, Asadi-Pooya et al. highlighted that LEV may be a better option than CBZ in the treatment of RLS due to its better tolerability and lower side effect profile. [22]

In our study, a rash severe enough to require treatment modification was observed in 1 patient from the LEV group, while the side effects observed in the other patients were mild and transient. When evaluating side effect profiles and tolerability, the overall side effect rate in our study, as well as in both treatment groups, was higher than reported in the literature. However, no significant difference was found between the two drugs in this regard. We believe that the small sample size may have contributed to this result. Additionally, the retrospective design and detailed medical record review may have led to a higher reported rate of mild adverse events compared to previous studies.

As a result, CBZ and LEV demonstrated similar efficacy in seizure control and EEG normalization in the treatment of RE. No significant difference was observed between the two drugs in terms of adverse effect profiles. However, given the small sample size and relatively short follow-up period, our study reflects real-life clinical practice and provides supportive evidence for the use of LEV as an effective monotherapy option in children with RE. Larger prospective studies with longer follow-up are needed to further evaluate potential differences in tolerability and long-term outcomes.

One of the strengths of this study is the direct comparison of levetiracetam and carbamazepine in children with Rolandic epilepsy within a real-world clinical setting. The evaluation of a relatively homogeneous patient population under similar follow-up conditions supports the internal consistency of the findings. However, the retrospective design introduces the potential for bias and limits the ability to establish causal relationships. The relatively limited sample size may affect the generalizability of the results. In addition, certain parameters that may influence treatment selection, such as long-term cognitive outcomes and cost-effectiveness, were not specifically assessed in this study. Future prospective studies with larger cohorts are needed to provide more robust evidence.

Conflict of Interest: The authors have no conflicts of interest to declare.

Researchers' Contribution Rate Statement: Concept/Design: FHT, CD; Analysis/Interpretation: FHT; Data Collection: FHT, MT; Writer: FHT, STO; Critical Review: FHT, MT, STO, CD; Approver: FHT, MT, STO, CD.

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