

# The Effect of Levetiracetam Monotherapy on Complete Blood Count Values and Inflammatory Markers in Long- and Short-term Treatment

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## Abstract

**Objective:** This study aimed to this study was to determine the effect of levetiracetam (LEV) monotherapy on complete blood count parameters and inflammatory markers at six and 12 months in children with epilepsy.

**Methods:** Files from 66 patients with epilepsy who were on LEV monotherapy were examined. Age, sex, and type of epilepsy, electroencephalography and cranial magnetic resonance imaging results at presentation, and complete blood count data at the start of treatment and at six and 12 months were recorded from the patients' files. Neutrophil-to-lymphocyte ratio (NLR), monocyte-to-lymphocyte ratio (MLR), platelet-to-lymphocyte ratio (PLR), and red cell distribution width/lymphocyte ratio (RDW/LYM) values were calculated from complete blood counts and used as inflammatory markers.

**Results:** The mean age of 66 patients was  $10.18 \pm 4.88$  years. The patients were equally distributed by gender. A comparison of complete blood parameters in patients receiving LEV monotherapy at baseline and at six and 12 months revealed a significant decrease in RDW values at 12 months ( $p < 0.05$ ), with no significant differences in other hematological parameters ( $p > 0.05$ ). Also, no significant differences were observed in inflammatory markers (NLR, MLR, PLR, and the RDW/LYM ratio) calculated from complete blood count parameters ( $p > 0.05$ ).

**Conclusion:** Use of LEV altered multiple complete blood count parameters. In addition, NLR, MLR, PLR, and the RDW/LYM ratio, recognized inflammatory markers, also changed during LEV therapy.

**Keywords:** Epilepsy, levetiracetam, complete blood count, inflammatory markers

## INTRODUCTION

Epilepsy is the most common neurological disorder in childhood, characterized by seizures.<sup>1</sup> Antiseizure medications (ASMs) are used to reduce the frequency and severity of such seizures. Since epilepsy frequently requires lifelong treatment, the objective, in addition to seizure control, is to protect patients as much as possible from treatment-related side effects and to enable them to maintain a good quality of life.<sup>2</sup> The evaluation and follow-up of potential side effects associated with treatment are therefore essential.

ASMs have broad adverse effects across multiple organ systems. One such system is the hematological system.<sup>3</sup> Studies have shown that they can cause side effects, including thrombocytopenia, leukopenia, leukocytosis, neutropenia, pancytopenia, pure red cell aplasia, aplastic anemia, macrocytosis, megaloblastic anemia, and bone marrow depression.<sup>4-6</sup>

Levetiracetam (LEV) is a new-generation ASM that has been frequently employed in recent years and is effective for secondary generalized tonic-clonic, focal, myoclonic, and primary generalized tonic-clonic seizures.<sup>7</sup> However, studies of the potential hematological side effects of LEV therapy are limited, and their results are inconsistent. Some studies investigating the side effects of LEV therapy have reported that, in addition to its systemic side effects, it can result in an unexplained increase in infections, such as pharyngitis and rhinitis.<sup>8-11</sup>

Various biomarkers are currently employed for the etiological and early diagnosis of infectious diseases, and for disease severity and response to treatment. White blood cell (WBC), neutrophil (NEU), platelet (PLT), red blood cell distribution width (RDW), lymphocyte (LYM), monocyte, and basophil values and parameters calculated from complete blood counts [the neutrophil-to-lymphocyte ratio (NLR), monocyte-to-lymphocyte ratio (MLR), platelet-to-lymphocyte ratio (PLR), and RDW/LYM] can be used as systemic inflammatory markers.<sup>12</sup>

Limited numbers of studies have investigated the effects of LEV therapy on complete blood count parameters, and none have investigated the potential effects on inflammatory markers obtained from complete blood counts. This study aimed to determine the effect of LEV monotherapy on complete blood count parameters and on inflammatory markers derived from those counts at six and 12 months in children with epilepsy.

## METHODS

### Study Design

Patients aged 0-18 years who were diagnosed with epilepsy based on International League Against Epilepsy diagnostic criteria and who received LEV monotherapy at the Balıkesir University Faculty of Medicine, Pediatric Neurology Clinic, Türkiye, between 01.08.2019 and 01.08.2022 were retrospectively included in the study. Patients with chronic diseases (liver disease, kidney disease, thyroid disease, or hematological disorder) who were using other drugs, who had a history of infection or antibiotic use in the previous two weeks, or who had missing file data were excluded.

There is no standardization concerning the follow-up of patients with epilepsy under treatment, although in our clinic and in the light of our patient numbers we follow-up our stable patients at three-month intervals. We also evaluate the hematological parameters of our patients every six months. However, we can also perform these follow-ups and evaluations more frequently, depending on clinical manifestations and symptoms.

Age, sex, type of epilepsy, electroencephalography (EEG) and cranial magnetic resonance imaging (MRI) results at presentation, and complete blood count data at the start of treatment and at six and 12 months were recorded from the patients' files in this study. NLR, MLR, PLR, and RDW/LYM ratio values were calculated from complete blood counts as inflammatory markers.

### MAIN POINTS

- A limited number of studies have investigated the effects of levetiracetam (LEV) therapy on complete blood count parameters, and none have investigated the potential effects of LEV therapy on inflammatory markers obtained from complete blood counts.
- LEV use altered various complete blood count parameters. In addition, neutrophil-to-lymphocyte ratio, monocyte-to-lymphocyte ratio, platelet-to-lymphocyte ratio, and red cell distribution width (RDW)/lymphocyte ratio values, recognized inflammatory markers, also changed with LEV therapy.
- We observed no clinical change in our patients. This finding indicates that attention to RDW values is required in patients using LEV. As with all drugs, it is important for patient safety that side effects of LEV use are reported to the relevant pharmacovigilance units.

Pre-treatment complete blood count parameters and inflammatory markers measured at six and 12 months of treatment were subjected to statistical comparisons. Approval from the Balıkesir University Clinical Research Ethics Committee was obtained prior to commencement (approval no: 2022/98, date: 07.09.2022).

### Statistical Analysis

Statistical analyses were performed using SPSS version 19.0. Categorical variables were presented as frequencies (n) and percentages (%), and complete blood count parameters and inflammatory markers were presented as mean±standard deviation. Statistical analysis was performed using a Bonferroni-corrected repeated-measures analysis of variance. P-values <0.05 were considered statistically significant.

## RESULTS

Sixty-six patients with a mean age of  $10.18 \pm 4.88$  years (1-18) were included in the analysis. The patients were equally distributed by gender (n=33, 50%). The patients were diagnosed with focal epilepsy, generalized epilepsy, or epilepsy of unknown cause and were receiving LEV monotherapy at doses of 20-25 mg/kg, administered as syrup (68.2%) or tablet (31.8%) forms. MRI and EEG findings at the start of treatment are shown in Table 1.

No differences by gender or pharmaceutical form were observed in complete blood count parameters at baseline, six months, or 12 months of treatment (p>0.05). A comparison of complete blood parameters in patients receiving LEV monotherapy at the beginning of treatment and after six and 12 months revealed a significant decrease in RDW values at 12 months (p<0.05), but no significant difference in other hematological parameters (p>0.05) (Table 2). No statistically significant differences were observed when we compared inflammatory markers (NLR, MLR, PLR, and the RDW/LYM ratio) calculated from complete blood count parameters (p>0.05) (Table 3).

**Table 1.** Demographic characteristics of patients using levetiracetam

Age	1-18 (10.18±4.88)
<b>Gender</b>	<b>n (%)</b>
Male	33 (50%)
Female	33 (50%)
<b>Seizure type</b>	<b>n (%)</b>
Focal	28 (42.4%)
Generalized	32 (48.5%)
Unknown	6 (9.1%)
<b>MRI</b>	<b>n (%)</b>
Normal	46 (69.7%)
Abnormal	20 (30.3%)
<b>EEG</b>	<b>n (%)</b>
Epileptiform	43 (65.2%)
Normal	18 (27.3%)
Abnormal	5 (7.6%)
<b>Drug pharmaceutical form</b>	<b>n (%)</b>
Syrup	45 (68.2%)
Tablet	21 (31.8%)

EEG: Electroencephalogram, MRI: Magnetic resonance imaging

**Table 2.** Complete blood count parameters of patients using levetiracetam

Complete blood count parameters	Before treatment	6 <sup>th</sup> month of treatment	12 <sup>th</sup> month of treatment	p
WBC (10 <sup>3</sup> /uL)	7.81±2.63	7.67±2.68	7.34±2.11	p=0.409
RBC (10 <sup>6</sup> /uL)	4.67±0.48	4.69±0.38	4.63±0.54	p=0.533
HB (g/dL)	12.50±1.82	12.88±1.01	12.83±1.11	p=0.357
HCT (%)	37.91±3.30	38.10±3.11	36.93±6.93	p=0.375
MCV (fL)	80.98±5.63	81.37±5.35	81.57±5.41	p=0.643
MCH (pg)	27.08±2.27	27.52±1.87	27.58±2.11	p=0.337
MCHC (g/dL)	33.41±0.85	33.81±0.75	33.77±1.03	p=0.085
RDW (%)	13.92±1.26	13.63±1.06	13.40±0.90*	p=0.013
PLT (10 <sup>3</sup> /uL)	301.77±88.12	297.06±83.55	303.53±84.39	p=0.803
PDW (%)	16.33±1.21	16.49±0.63	16.47±0.43	p=0.537
PCT (%)	0.24±0.06	0.25±0.10	0.25±0.05	p=0.924
NEU (10 <sup>6</sup> /uL)	4.14±2.14	3.92±2.61	3.61±1.59	p=0.367
LYM (10 <sup>3</sup> /uL)	2.76±1.42	3.14±1.67	2.90±1.30	p=0.409
MON(10 <sup>3</sup> /uL)	0.59±0.24	0.59±0.22	0.62±0.36	p=0.186
EOS (10 <sup>3</sup> /uL)	0.19±0.19	0.19±0.20	0.20±0.21	p=0.976
BAS (10 <sup>3</sup> /uL)	0.03±0.05	0.03±0.06	0.03±0.06	p=0.876
NEU%	52.28±14.50	48.02±14.38	48.69±12.67	p=0.196
LYM%	36.45±13.21	40.87±13.10	39.64±11.86	p=0.191
MON%	7.79±2.72	7.87±2.27	8.24±2.57	p=0.370
EOS%	2.75±2.86	2.65±2.55	2.63±2.69	p=0.929
BAS%	0.64±0.43	0.61±0.63	0.58±0.37	p=0.244

Compared with pre-treatment values; \*: p<0.05. WBC: White blood cell, HB: Hemoglobin, HCT: Hematocrit, RDW: Red blood cell distribution width, PLT: Platelet, MPV: Mean platelet volume, NEU: Neutrophil, LYM: Lymphocyte, MON: Monocyte, EOS: Eosinophil, BAS: Basophil, RBC: Red blood cell, HB: Hemoglobin, MCV: Mean corpuscular volume, MCH: Mean corpuscular hemoglobin, MCHC: Mean corpuscular hemoglobin concentration, PDW: Platelet distribution width, PCT: Plateletcrit

**Table 3.** Inflammatory markers of patients using levetiracetam

Complete blood count parameters	Before treatment	6 <sup>th</sup> month of treatment	12 <sup>th</sup> month of treatment	p
NLR	1.89±1.50	1.53±1.16	1.48±0.95	p=0.277
MLR	0.25±0.15	0.21±0.08	0.24±0.16	p=0.364
PLR	129.47±61.94	112.33±47.69	117.22±41.31	p=0.533
RDW/LYM	6.27±3.88	5.27±2.07	5.42±2.14	p=0.065

NLR: Neutrophil to lymphocyte ratio, PLR: Platelet to lymphocyte ratio, MLR: Monocyte to lymphocyte ratio, RDW/LYM: Red cell distribution width/lymphocyte ratio

## DISCUSSION

Epilepsy is a severe neurological disorder frequently encountered in childhood, and one that often requires lifelong treatment.<sup>1</sup> ASMs can give rise to various systemic side effects, including hematological ones.<sup>13,14</sup> While the mechanisms underlying the hematological side effects of ASMs are not yet fully understood, various mechanisms have been proposed, such as direct toxic effects of the drugs, increased levels of toxic metabolites and homocysteine, decreased folic acid levels, and direct effects of the drugs on cells. The observation that side effects, such as neutropenia, typically emerge within the first two weeks after medication exposure and resolve within the first few days after drug discontinuation suggests that immunological mechanisms may also contribute to the pathophysiology.<sup>13</sup> Potential pharmacokinetic and pharmacodynamic drug interactions may also affect the emergence of hematological side effects.

LEV is a new-generation ASM.<sup>7</sup> It is widely used in children due to its broad spectrum of effects, low side-effect profile, and ease of administration.<sup>15-17</sup> Preparations containing LEV are available under various trade names and in tablet, oral solution, and infusion forms. We consider both patient age and preference when prescribing medications in our clinic. We may encounter patients and parents who prefer the liquid formulation at ages when tablets can be used. We also have patients whom we initially start on tablets but subsequently switch to the syrup formulation because of poor adherence. In this study, our patients were diagnosed with focal, generalized, or unknown epilepsy and were receiving LEV monotherapy in syrup (68.2%) and tablet (31.8%) forms.

The most frequently reported side effects among patients receiving LEV therapy are somnolence, asthenia, and dizziness.<sup>8</sup> Few studies have examined the LEV therapy on hematological parameters. Some of these studies have reported that LEV use produces changes in complete blood count parameters and even

side effects such as anemia and pancytopenia.<sup>17-24</sup> Similar to other ASMs, the mechanism underlying the hematological changes reported with LEV use remains unclear. A potential association has been reported between pancytopenia and bone marrow aplasia, and between anemia and folic acid deficiency.<sup>25</sup> It has been suggested that immune mechanisms may play a role in the development of thrombocytopenia<sup>26</sup> and that synaptic vesicle protein 2A, regarded as the site of action of LEV, is associated with PLT expression.<sup>27</sup>

Some studies evaluating the side effects of LEV therapy have reported an unexplained increase in the incidence of infections, such as pharyngitis and rhinitis.<sup>8-11</sup> The reason for that increase is still unknown. Some complete blood count parameters are known to be associated with systemic inflammation. WBC counts and their subtypes, including LYMs, as markers of the immune system, are known to play a role in inflammation. PLTs are also involved in blood clotting during various inflammatory events. PLT distribution width, in addition to PLT counts, is used to estimate PLT function and activation.<sup>28,29</sup>

Cohort studies have also shown an association between RDW, a complete blood count parameter, and inflammatory processes.<sup>30</sup> The NLR, PLR, MLR, and the RDW/LYM ratio have recently emerged as predictors of systemic inflammation and as novel markers correlated with prognosis.<sup>12,31-33</sup> These markers are easily obtained and calculated from complete blood counts and are relatively inexpensive.

Studies investigating the hematological effects of ASMs have focused on changes in cell numbers in complete blood counts, and very few have included an evaluation of inflammatory markers. The number of studies examining changes in cell counts from complete blood counts in patients treated with LEV is also quite low. Studies have shown that NEU and leukocyte counts were within normal ranges in patients using LEV who developed infection;<sup>17</sup> however, no previous studies have evaluated the effects of LEV on inflammatory markers (NLR, MLR, PLR, and RDW/LYM ratios). The present study compared inflammatory markers, calculated from complete blood count parameters, at baseline and after six and 12 months of treatment in patients receiving LEV monotherapy. When we compared complete blood parameters in patients receiving LEV monotherapy at the beginning of treatment and after 6 and 12 months, we observed a significant decrease in RDW values after 12 months ( $p<0.05$ ). However, there were no significant differences in other hematological parameters ( $p>0.05$ ; Table 2). Also, No significant differences were observed when we compared inflammatory markers (NLR, MLR, PLR, RDW/LYM ratio) calculated from complete blood count parameters ( $p>0.05$ ; Table 3).

## Study Limitations

In our clinic, we initiate our patients on the lowest recommended daily therapeutic dose specified in the drug prospectus (20 mg/kg/day). However, we may raise this to as much as 40 mg/kg/day, depending on the response to treatment. This study evaluated changes in hematological parameters and inflammatory markers at 6 and 12 months of treatment in a limited number of patients receiving 20-25 mg/kg/day LEV monotherapy. The drug dosage and duration may affect the patient's response to treatment and may also influence the occurrence of adverse effects. Further prospective studies, including more patients and using LEV

for different durations, especially at higher doses, are needed to examine the relationship between LEV treatment and inflammatory markers, a finding revealed for the first time in this study.

## CONCLUSION

This research represents one of the few studies to evaluate potential changes in complete blood count parameters in association with LEV therapy. This study is important because it investigates, for the first time in the literature, the relationship between LEV therapy and the inflammatory parameters NLR, MLR, PLR, and the RDW/LYM ratio, and demonstrates that RDW values, which have been linked to inflammatory processes, can change in response to LEV therapy.

Differences among study results evaluating complete blood count parameters suggest that treatment duration and drug dosage may influence the observed effects. The present study evaluated, in a limited number of patients receiving 20-25 mg LEV monotherapy, changes in hematological parameters and inflammatory markers at six and 12 months. The changes in inflammatory markers associated with LEV use, first reported in this study, should be examined in further studies evaluating different dosages, treatment durations and larger patient cohorts.

Although we observed no clinical change in our patients, the findings indicate that monitoring RDW values is warranted in patients using LEV. As with all drugs, it is important in terms of patient safety for side-effects of LEV use to be reported to the relevant pharmacovigilance units.

## Ethics

**Ethics Committee Approval:** Approval from the Balikesir University Clinical Research Ethics Committee was obtained prior to commencement (approval no: 2022/98, date: 07.09.2022).

**Informed Consent:** Retrospective study.

## Footnotes

## Authorship Contributions

Surgical and Medical Practices: H.A., Concept: O.K., H.A., Design: O.K., Data Collection or Processing: H.A., Analysis or Interpretation: O.K., Literature Search: O.K., H.A., Writing: O.K., H.A.

**Conflict of Interest:** No conflict of interest was declared by the authors.

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