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Original Scientific Paper

CORTICOSTEROIDS IN THE MANAGEMENT OF PEDIATRIC EPILEPSIES

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SUMMARY – Epilepsy is one of the most common chronic diseases in children, and cannot be controlled with conventional antiepileptic drugs in 30% of cases. Therefore, in these cases, alternative approach such as corticosteroid therapy (CT) is used. The aim of this study was to analyze different types of CT used to treat drug-resistant childhood epilepsies, treated at Rijeka University Hospital Centre during a 5-year period (2016-2020). This retrospective study included 32 patients. The following parameters were analyzed: number of patients with a particular diagnosis, average age (in months) at the onset of epilepsy, average epilepsy duration (in months) prior to CT, average number of antiepileptic drugs used prior to CT, presence of changes on magnetic resonance imaging (MRI), presence of comorbidities, and types of CT. The average age at the onset of epilepsy was 14 months and average epilepsy duration prior to CT was 16 months. On average, 5 antiepileptic drugs were used prior to CT. MRI changes were present in 53.13% and comorbidities in 81.25% of study patients. Prednisone therapy was used in 28.13%, combined therapy with prednisone and methylprednisolone in 65.63%, and methylprednisolone in 6.25% of patients. Study results revealed the use of CT for particular diagnosis to differ among the centers, as well as within the same center, so it is important to highlight the importance of reaching universal guidelines for CT therapy of childhood epilepsies.

Key words: *Epilepsy, pharmacoresistant; Corticosteroids; Guidelines*

Introduction

Epilepsy is one of the most common chronic diseases in children and affects 0.5% to 1% of pediatric population[1]. Classification of epilepsy is the key factor in assessing an individual with a distinct type of seizure. It provides a starting point for therapeutic approach and allows understanding of the further course of the disease and possible accompanying conditions such as regression in cognitive and mental development. Epilepsy is classified by classifying the type of seizure, then the type of epilepsy and then, if possible, classifying it into a specific epileptic syndrome. Epilepsies are also classified according to their etiology and are divided into metabolic, genetic, structural, infectious, immune and epilepsy of unknown cause[2].

Unfortunately, the cause of numerous epileptic seizures remains unknown, therefore etiologic treatment remains unattainable. Today's therapeutic approach tries to achieve complete seizure control and strives to improve the quality of life. Drug-resistant epilepsy (DRE) is defined as a failure of adequate trials of two tolerated, appropriately chosen and used antiepileptic drug (AED) schedules (either as monotherapy or in combination) to achieve sustained seizure freedom[3]. There are different pharmacological and non-pharmacological methods in the management of epilepsy. Non-pharmacological therapy includes surgical therapy, vagus nerve stimulation, and a ketogenic diet. A

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significant amount of time has also been devoted to researching the role of corticosteroid treatment (CT) in drug resistant epilepsies.

Adrenocorticotropic hormone (ACTH) first showed its effectiveness in treating drug resistant epilepsies in the 1950s. Eight years later, its specific therapeutic activity in infantile spasms was described[4]. Since the beginning of using CT and ACTH, there are no established guidelines for their use in the management of drug-resistant epilepsies, except for the case of West syndrome[4]. Numerous studies have attempted to investigate which CT is optimal, however, the results of those studies vary a lot. While older studies favor ACTH, newer studies show no differences in the efficacy of ACTH and oral corticosteroids. Moreover, oral corticosteroids are preferred for avoiding unnecessary hospitalizations[5]. Despite numerous hypotheses, the antiepileptogenic mechanism of action of corticosteroids is still unknown. Side effects must be kept in mind when prescribing corticosteroids.

There are two types of ACTH, natural and synthetic. The first formulation is not available in Europe, and the second formulation, which exhibits prolonged action, is not available in the USA[6]. Given the high price of ACTH, oral corticosteroids are the first-line treatment in many countries. Evidence suggests that low doses are as effective as high doses for short-term treatment[6]. ACTH is used in the management of infantile spasms at Osijek University Hospital Centre and Zagreb Children's Hospital, applying Riikonen regimen[7]. In all cases, treatment starts with tetracosactide at a dose of 0.03 mg/kg every 2nd day and then assessment is performed at 2 weeks. For cryptogenic infantile spasms which are responding to treatment, tetracosactide is prescribed at a dose of 0.015 mg/kg every 2nd day in 3rd week and at a dose of 0.0075 mg/kg every 2nd day in 4th week. For symptomatic infantile spasms which are responding to treatment in 3rd and 4th week, tetracosactide is prescribed at a dose of 0.03 mg/kg every 2nd day. In 5th week, half dose is administered each week every 2nd day. For cryptogenic and symptomatic infantile spasms which are not responding to treatment in 3rd and 4th week tetracosactide is prescribed at a dose of 0.06 mg/kg every 2nd day. In 5th week half dose is administered. Nitrazepam, valproate, vigabatrin, topiramate and zonisamide are added as necessary. If relapse occurs, ACTH should be returned to the lowest preceding effective dose. At Sestre milosrdnice University Hospital Centre, intramuscular tetracosactide is administered at a dose of 500 μg every 2nd day for 14 days, with the possibility of increasing the dose to 750 μg if there is no remission after 7 days of use.

Although ACTH is used in numerous centers, research has not shown it to be superior to prednisone. Moreover, the proportion of patients with expressive communication and fine motor skill delay was significantly higher in the ACTH group at the age of two years[8]. At Sestre milosrdnice University Hospital Centre, prednisone is used for the treatment of infantile spasms, at a dose of 40 mg divided in 2 or 4 daily doses per os for 2 to 4 weeks. The use of hybrid corticosteroid regimen composed of initial pulses of methylprednisolone followed by low-dose oral prednisolone in the treatment of DRE is as effective as the use of high-dose oral prednisolone from the start but with less adverse effect profile[9,10]. At Sestre milosrdnice University Hospital Centre, intravenous methylprednisolone in pulse therapy is used for the treatment of encephalopathies and DRE. It is prescribed at a dosage of 250 to 500 mg for 3 to 5 days depending on the situation, age, and electroencephalography findings.

In West syndrome, pulsatile dexamethasone therapy is an effective alternative treatment to ACTH[5]. Dexamethasone is used at Osijek University Hospital Centre and Zagreb Children's Hospital. Zagreb Children's Hospital uses dexamethasone for epileptic encephalopathies in patients older than 2 years. It is prescribed at a dose of 20 mg/m^2 divided in 4 daily doses administered intravenously for 3 days every 4 weeks over 6-month period. At Osijek University Hospital Centre, dexamethasone is used for electrical status epilepticus in sleep (ESES) and other epileptic encephalopathies. It is prescribed at a dosage of 1 to 1.2 mg/kg daily divided in 4 doses for 3 days. That scheme is repeated every 28 days. If clinical outcome is good, the regimen is continued for 6 months, and if not, the protocol is terminated after 3rd cycle.

The aim of our study was to analyze different types of CT used for the treatment of DRE at Rijeka University Hospital Centre.

Patients and Methods

Data were collected retrospectively during a 5-year period (2016-2020). Research was conducted in accor-

dance with Helsinki Declaration. The source of data was medical documentation from computer based hospital system of Rijeka University Hospital Centre and our Centre registry of epilepsies. The diagnosis of epilepsy was made according to 2014 guidelines set by the International League Against Epilepsy[11]. Corticosteroid therapy was administered based on global recommendations and experience, respecting good medical practice and experience of working in a tertiary health care institution. We included 32 patients with DRE in the study. Analysis included general characteristics of the examined group and characteristics according to the syndrome and etiology classification. According to syndrome classification, patients were divided into 4 groups, as follows: 1) electrical status epilepticus during slow-wave sleep (ESES), continuous spike and wave during slow wave sleep (CSWS) and Landau-Kleffner syndrome (LKS); 2) West syndrome; 3) early-onset epileptic encephalopathy (Dravet syndrome, Ohtahara syndrome, early myoclonic encephalopathy); and 4) epilepsy of unknown syndrome. ESES and Landau-Kleffner syndrome and CSWS are classified in the same group due to the overlap of these syndromes. Early-onset epileptic encephalopathy is characterized by the onset of epilepsy within the first year of life. According to etiologic classification, patients were divided into 3 groups, as follows: genetic epilepsy, structural epilepsy, and epilepsy of unknown etiology. There were no patients with metabolic, immune and infectious etiology of epilepsy in this study. The following characteristics were analyzed: number of patients with certain diagnosis, average age (in months) at onset of epilepsy, average epilepsy duration (in months) prior to CT, average number of AEDs used prior to CT, presence of morphological abnormalities on magnetic resonance imaging (MRI), and presence of comorbidities. The most common comorbidities were cerebral palsy, intellectual disability, and delayed development. The type of administered CT in the entire research group and type of CT according to the syndrome and etiologic classification were also analyzed. Furthermore, doses and duration of prednisone therapy were analyzed. Prednisone was administered *per os* in high or low doses. High doses were considered those of 40 to 60 mg *per* day, and low doses all doses less than these. Intravenous methylprednisolone pulse therapy was administered at a dose of 500 mg for 3 days. Combination therapy implied initial pulses of methylprednisolone followed by prednisone until complete reduction of seizures.

Data are expressed as absolute numbers, percentage and descriptive statistics (median, mode, minimum, maximum).

Results

General characteristics of study patients are shown in Table 1. A total of 32 patients participated in this study, 16 male and female each, age range from 10 months to 16 years (median, 8 years and 6 months). Average age at onset of epilepsy was 14 months (mode 7; min 1– max 149). On average, 5 (mode 2; min 2 – max 12) AEDs were used prior to CT. Average epilepsy duration prior to CT was 6 months (mode 0; min 0 – max 84). Morphological abnormalities on MRI were present in 53.13% (17/32) and comorbidities were present in 81.25% (26/32) of patients.

Table 1. General characteristics of study patients (N=32)

Sex	Male 16/ Female 16
Average age at onset of epilepsy (months)	14 (7) min 1 – max 149
Average number of antiepileptic drugs used prior to corticosteroid therapy	5 (2) min 2 – max 12
Average epilepsy duration prior to corticosteroid therapy (months)	6 (0) min 0 – max 84
Presence of MRI changes	17 [53.13%]
Presence of comorbidities	26 [81.25%]

MRI = magnetic resonance imaging; mode shown in brackets

Table 2 shows characteristics of patient groups according to etiologic classification. Structural epilepsy was identified in 40.62% (13/32) of patients, including eight female and five male patients. Average age at onset of epilepsy was 9 months (mode /; min 4 – max 96). On average, 4 (mode 2; min 2 – max 7) AEDs were used prior to CT. Average epilepsy duration prior to CT was 6 months (mode 0; min 0 – max 84). Morphological abnormalities on MRI, as well as comorbidities were present in all 13 patients.

Genetic epilepsy was identified in 21.88% (7/32) of patients, two female and five male patients. Average age at onset of epilepsy was 7 months (mode 7; min 1

Table 2. Characteristics of patient groups according to etiologic classification

		Structural	Genetic	Unknown etiology
Total number of study patients (N=32)		13 (40.62%)	7 (21.88%)	12 (37.5%)
Sex	Female	8	2	6
	Male	5	5	6
Average age at onset of epilepsy (months)		7 (7) min 1 – max 24	9 (/) min 4 – max 96	41 (/) min 3 – max 149
Average number of antiepileptic drugs used prior to corticosteroid therapy		4 (2) min 2 – max 7	10 (10) min 2 – max 12	4 (4) min 2 – max 10
Average epilepsy duration prior to corticosteroid therapy (months)		6 (0) min 0 – max 84	6 (/) min 0 – max 57	7 (0) min 0 – max 60
Presence of MRI changes		13	3	1
Presence of comorbidities		13	7	6

MRI = magnetic resonance imaging; mode shown in brackets; / = mode not possible to count

Table 3. Characteristics of patient groups according to syndrome classification

		Early-age epilepsy	West syndrome	ESES/CSWS/LKS	Unknown syndrome
Total number of respondents (N=32)		7 (21.88%)	11 (34.38%)	11 (34.38%)	3 (9.38%)
Sex	Female	3	5	7	1
	Male	4	6	4	2
Average age at onset of epilepsy (months)		3 (3) min 1– max 20	7 (7) min 4 – max 27	40 (/) min 16 – max 149	42 (/) min 40 – max 44
Average number of antiepileptic drugs used prior to corticosteroid therapy		6 (10) min 4 – max 10	4 (2) min 2 – max 12	4 (/) min 2 – max 7	4 (/) min 3 – max 5
Average epilepsy duration prior to corticosteroid therapy (months)		6 (/) min 0 – max 84	2 (0) min 0 – max 19	12 (0) min 0 – max 84	3 (/) min 1 – max 12
Presence of MRI abnormalities		6	8	3	0
Presence of comorbidities		7	11	6	2

CSWS = continuous spike and wave during slow wave sleep; ESES = electrical status epilepticus during slow-wave sleep; LKS = Landau-Kleffner syndrome; MRI = magnetic resonance imaging; mode shown in brackets; / = mode not possible to count

– max 24). On average, 10 (mode 10; min 2 – max 12) AEDs were used prior to CT. Average epilepsy duration prior to CT was 6 months (mode /; min 0 – max 57). Morphological changes on MRI were present in three patients and comorbidities in all seven patients.

Epilepsy of unknown etiology was identified in 37.50% (12/32) of patients, six female and male patients each. Average age at onset of epilepsy was 41 months (mode /; min 3 – max 149). On average, 4 (mode 4; min 2 – max 10) AEDs were used prior to CT. Average epilepsy duration prior to CT was 7 months (mode 0; min 0 – max 60). Morphological changes on MRI were present in one patient and comorbidities in six patients.

Table 3 shows characteristics of patient groups according to syndrome classification. Early-onset epilepsy was diagnosed in 21.88% (7/32) of patients, three female and four male patients. Average age at onset of epilepsy was 3 months (mode 3; min 1 – max 20). On average, 6 (mode 10; min 4 – max10) AEDs were used prior to CT. Average epilepsy duration prior to CT was 6 months (mode /; min 0 – max 84). Morphologi-

cal changes on MRI were present in six patients and comorbidities in all seven patients. West syndrome was identified in 34.38% (11/32) of patients, five female and six male patients. Average age at onset of epilepsy was 7 months (mode 7; min 4 – max 27). On average, 4 (mode 2; min 2 – max 12) AEDs were used prior to CT. Average epilepsy duration prior to CT was 2 months (mode 0; min 0 – max 19). Morphological abnormalities on MRI were present in eight patients and comorbidities in all 11 patients. ESES/CSWS/LKS was identified in 34.38% (11/32) of patients, seven female and four male patients. Average age at onset of epilepsy was 40 months (mode /; min 16 – max 149). On average, 4 (mode /; min 2 – max 7) AEDs were used prior to CT. Average epilepsy duration prior to CT was 12 months (mode 0; min 0 – max 84). Morphological abnormalities on MRI were present in three patients and comorbidities in all six patients.

Epilepsy of unknown syndrome was identified in 9.38% (3/32) of patients, one female patient and two male patients. Average age at onset of epilepsy was 42 months (mode /; min 40 – max 44). On average, 4 (mode /; min 3 – max 5) AEDs were used prior to CT. Average epilepsy duration prior to CT was 3 months (mode /; min 1 – max 12). Morphological abnormalities on MRI were not recorded in these patients, while comorbidities were found in two patients.

Table 4 shows administration of corticosteroids to study groups. Prednisone was administered to 28.13% (9/32), combination therapy with prednisone and methylprednisolone to 65.63% (21/32), and methylprednisolone to 6.25% (2/32) of patients.

Table 4a shows types of CT according to etiologic classification. In the group of 13 patients with structural epilepsy, three patients received prednisone, eight patients received combination therapy, and two pa-

Table 4. Administration of corticosteroids to study patients

Prednisone	9 (28.13%)
Combination therapy	21 (65.63%)
Methylprednisolone	2 (6.25%)
Total	(100%)

Table 4a. Types of corticosteroid therapy according to etiologic classification

	Structural	Genetic	Unknown etiology	Total
Prednisone	3	1	5	9
Combination therapy	8	6	7	21
Methylprednisolone	2	0	0	2

Table 4b. Types of corticosteroid therapy according to syndrome classification

	Early-age epilepsy	West syndrome	ESES/CSWS/LKS	Unknown syndrome
Prednisone	1	3	3	2
Combination therapy	5	8	7	1
Methylprednisolone	1	0	1	0

CSWS = continuous spike and wave during slow wave sleep; ESES = electrical status epilepticus during slow-wave sleep; LKS = Landau-Kleffner syndrome

Table 5. Duration of prednisone therapy (N=30)

	Total number of patients	Minimum (days)	Maximum (days)	Median
Low-dose	7	20	84	37
High-dose	23	21	105	45
Total	30	20	105	42

tients received methylprednisolone. In the group of seven patients with genetic epilepsy, one patient received prednisone and six patients received combination therapy. In the group of 12 patients with epilepsy of unknown etiology, five patients received prednisone and seven patients received combination therapy. Genetic epilepsies and epilepsies of unknown etiology were not treated with methylprednisolone.

Table 4b shows types of CT according to syndrome classification. In the group of seven patients with early-onset epilepsies, one patient received prednisone and methylprednisolone each, while the remaining five patients received combination therapy. In the group of 11 patients with West syndrome, three patients received prednisone and eight patients received combination therapy. None of these patients received methylprednisolone. In the group of 11 patients with ESES/CSWS/LKS, three patients received prednisone, seven patients received combination therapy, and one patient received methylprednisolone. In the group of three patients with epilepsy without syndrome diagnosis, two patients received prednisone and one patient received combination therapy. None of these patients received methylprednisolone.

Table 5 shows duration of prednisone administered either as monotherapy or as part of combination therapy. A total of 30 patients received prednisone for a minimum of 20 days, maximum of 105 days, and median of 42 days. In seven (7/30) patients, prednisone was administered according to low-dose regimen. Minimum duration of low-dose prednisone therapy was 20 days, maximum 84 days, and median 37 days. In 23 (23/30) patients, prednisone was administered according to high-dose regimen. Minimum duration of high-dose prednisone therapy was 21 days, maximum 105 days, and median 45 days.

Discussion

Therapy of DRE presents a major challenge. In our study, there was no sex difference in the incidence of epilepsy, as illustrated in Table 1. The incidence of epilepsy was highest in infancy, where the most common age at diagnosis of epilepsy was 7 months (Table 1). Early age at onset of epilepsy has been shown to be a predictive factor for drug-resistant epilepsy[12].

Epilepsy is one of the most common chronic diseases in children, but its etiology remains obscure in more than half of the cases[13]. In this study, the etiology was unknown in 37.50% of patients (Table 2). Numerous genetic tests and neuroimaging methods have led to significant improvement in detecting the cause of epilepsy, however, further research is needed to contribute to better understanding of this disease.

Only one-third of epilepsies can now be classified as a specific epileptic syndrome[13]. In this study, 9.38% of patients with DRE were not classified as specific epileptic syndrome, which is a satisfactory fact given that knowledge of epileptic syndrome allows us to know appropriate treatment, prognosis and comorbidities associated with the syndrome.

Corticosteroid therapy is one of the alternative methods of pharmacological epilepsy treatment. Average epilepsy duration prior to CT varies greatly among studies. Tables 1, 2 and 3 show that on average 6 or less months had elapsed from the diagnosis of epilepsy to initiating CT at our Centre, which is significantly less than in other studies. In contrast, the number of AEDs used prior to the introduction of CT correlates with other studies, with 4 to 5 AEDs being most commonly reported.

Algorithms for the use of CT for drug resistant epilepsy are still not available, as clearly indicated in this study. In addition to the type of CT, Tables 4, 4a, 4b and 5 show that differences were also present in corticosteroid doses and duration of treatment. Table 4 clearly shows that combination therapy with *per os* prednisone and intravenous methylprednisolone was the most common method of treatment (in 65.63% of patients) at our Centre. Table 5 shows that high doses of prednisone were most commonly used, either as monotherapy or in combination with methylprednisolone. This does not correlate with some other studies, suggesting that low doses of prednisone should be used in combination therapy because the goal is to reduce side effects[9,10]. However, high-dose prednisone monotherapy correlates with other studies. The initial dose of prednisone therapy is followed by a period of dose tapering. Duration of that period varied greatly in this study.

In other studies and at Osijek University Hospital Centre, Zagreb Children's Hospital and Sestre milosrdnice University Hospital Centre, ACTH is used for the treatment of infantile spasms. In contrast, ACTH was not used at our Centre. Moreover, Tables 4, 4a and 4b show that combination therapy was predominantly used.

This research revealed that all three CT types were used in the treatment of ESES/CSWS/LKS in our Centre; however, most common were combination therapy and prednisone therapy. In other studies, continuous dexamethasone therapy or methylprednisolone pulse therapy have been shown to be effective[5]. Furthermore, Tables 4, 4a and 4b show that although dexamethasone therapy has been shown to be effective in case of ESES and West syndrome, it was not used in our study. In the case of Lennox-Gastaut syndrome, it is assumed that corticosteroids may be effective, but their efficacy has not been proven. In our study, only weight gain was recorded as an adverse effect of CT.

Conclusion

There are differences in corticosteroid treatment for drug resistant epilepsies among different centers, as well as within the same center. It is important to emphasize the importance of developing general guidelines for corticosteroid treatment of childhood epilepsies.

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Sažetak

PRIMJENA KORTIKOSTEROIDA U LIJEČENJU EPILEPSIJA RAZVOJNE DOBI

I. Prpić, I. Blažeković, J. Radić Ništević i *I. Kolić*

Epilepsija je jedna od najčešćih kroničnih bolesti u djece, a u oko 30% djece primjena standardnih antiepileptičkih lijekova (AEL) ne dovodi do smanjenja broja napadaja. Stoga se u liječenju primjenjuju dodatne mogućnosti liječenja poput kortikosteroida. Cilj ovoga istraživanja bio je analizirati načine primjene kortikosteroidne terapije (KT) farmakorezistentnih epilepsija razvojne dobi u djece liječene u Kliničkom bolničkom centru Rijeka. Istraživanje je provedeno retrospektivno tijekom razdoblja od 5 godina (2016.-2020.). Analiziran je ukupan broj bolesnika s određenom dijagnozom, prosječna dob kod postavljanja dijagnoze epilepsije, prosječno trajanje epilepsije prije uvođenja KT, prosječan broj primijenjenih AEL prije uvođenja KT, prisutnost promjena na magnetskoj rezonanciji (MR), prisutnost komorbiditeta te vrsta primijenjene KT. Prosječna dob kod postavljanja dijagnoze epilepsije iznosila je 14 mjeseci, dok je prosječno trajanje epilepsije prije uvođenja KT bilo 6 mjeseci. Ispitanici su prosječno koristili 5 AEL prije uvođenja KT. MR promjene bile su prisutne u 53,13% bolesnika, a komorbiditeti u njih 81,25%. Prednizon se primjenjivao u 28,13%, kombinirana terapija u 65,63%, a metilprednizolon u 6,25% bolesnika. Različitosti u primjeni KT utvrđene su na razini istog centra, ali i među različitim centrima pa se ističe nužnost uvođenja smjernica za primjenu KT u liječenju epilepsija razvojne dobi.

Ključne riječi: *Epilepsija, farmakorezistentna; Kortikosteroidi; Smjernice*