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Treatment of pediatric epilepsy in Poland

Dorota Dunin-Wąsowicz [a], *Maria Mazurkiewicz-Bełdzińska* [b], *Barbara Steinborn* [c], *James Wheless* [d,e], *Sergiusz Jóźwiak* [a,*]

[a] *Department of Neurology and Epileptology, The Children's Memorial Health Institute, Warsaw, Poland*
[b] *Department of Developmental Neurology, Chair of Neurology, Medical University of Gdańsk, Poland*
[c] *Chair, Department of Developmental Neurology, Poznań University of Medical Sciences, Poland*
[d] *University of Tennessee Health Science Center, Memphis, TN, USA*
[e] *Le Bonheur Children's Hospital, Memphis, TN, USA*

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ABSTRACT

Background: The many types of childhood epilepsies make the diagnosis and treatment difficult and the outcomes frequently poor. Furthermore, there are few clinical trials in pediatric epilepsy that provide useful results to guide daily practice. Therefore for pediatric neurologists expert opinion may be useful.
Aims: To provide an overview of current practice in Poland and compare results with European and US clinical guidelines.
Methods: Polish specialists in pediatric neurology were asked to participate in a survey about pediatric epilepsy. The focus of the questions was on the overall strategy and treatment options for different syndromic diagnoses. The survey was developed and performed according to a previous European survey (Wheless et al., 2007).
Results: Fifty-one Polish specialists, working in academic or clinical settings, completed the questionnaire. They limited combination therapy to two or three antiepileptic drugs. Valproate was the treatment of choice for myoclonic, generalized tonic-clonic seizures and Lennox-Gastaut syndrome. For infantile spasms caused by tuberous sclerosis and of symptomatic etiology, vigabatrin was treatment of choice; valproate and ACTH were other first line options. Valproate and ethosuximide were chosen for childhood absence epilepsy and valproate for juvenile absence epilepsy. Carbamazepine was the first-line treatment option for benign partial epilepsy of childhood with centrotemporal spikes and complex partial seizures. In the treatment of juvenile myoclonic epilepsy for males valproate, for females lamotrigine were chosen.
Conclusion: Polish pediatric neurologists agreed on the majority of questions. Their views reflect the clinical utility and availability of treatment options in Poland. Results may provide direction for clinicians.

* *Corresponding author*. Department of Neurology and Epileptology, The Children's Memorial Health Institute, Al. Dzieci Polskich 20, 04-730 Warsaw, Poland. Tel.: +48 22 8157447.
E-mail address: sergiusz.jozwiak@gmail.com (S. Jóźwiak).
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1. Introduction

Epilepsy and epileptic syndromes are among the most common neurological disorders in childhood and adolescence with a prevalence of 5.3–8.8 per 1000 in children below 13 years of age.[1] Compared with adult epilepsies, childhood epilepsies present a much more heterogenous group of conditions, each characterized by varied diagnostic criteria, and frequently specific management requirements and different outcomes.

In recent years, many new antiepileptic drugs (AEDs) have been brought to the market, five between 2009 and 2011 alone in the US.[2] At present there are 24 AEDs, as well as vagus nerve stimulation (VNS) approved for use in the treatment of epilepsy by the Food and Drug Administration in the United States.[2] Improvements in neurosurgical techniques have also made the surgical treatment of patients with refractory partial seizures more effective and safer. Ketogenic diet and its modifications are offered in increasing number of centers worldwide.[3,4] Even with this increasing number of new therapies, 30–35% of patients suffer from drug-resistant epilepsy. Expanding therapeutic options present a challenge to the physician in terms of choosing the optimal therapeutic agent for an individual patient. This situation has necessitated the development of therapeutic guidelines to assist the physician in the decision-making process.

Guidelines from the Therapeutics and Technology Assessment Subcommittee and Quality Standard Subcommittee of the American Academy of Neurology and the American Epilepsy Society practice parameters for the use of new AEDs were first published in 2004[5] and are currently being updated.

In 2006, the International League Against Epilepsy (ILAE) for the first time published evidence-based treatment guidelines for initial monotherapy based on an extensive review of the literature from 1940 to 2005.[6] The authors analyzed results from 50 randomized controlled trials and 7 meta-analyses. This document noted an alarming lack of well-designed, randomized controlled trials, especially in children. Results of only four trials were classified as class I evidence and two as class II evidence.[6] Remaining studies were classified as class III or IV evidence. Thus, the strongest recommendation (level A) in childhood epilepsy was available only in partial-onset seizures (oxcarbazepine). In other types of childhood epilepsies only low level of evidence were available (level C). Despite the ever-growing body of evidence in the medical literature regarding the treatment of epilepsy, many routine clinical questions remain unanswered or only partially answered.

An update published in 2013 including 64 randomized studies and 11 meta-analyses - up to 2012. There were only 3 additional studies with class I evidence. The change in childhood epilepsy therapy was level A evidence for valproate and ethosuximide in absence epilepsy. The authors once again reported their concern over the general lack of high level evidence studies in children.[7]

Very few of the clinical trials on these common childhood epilepsies have compared different treatments with each other. Moreover, many controlled trials do not include childhood epilepsies or epilepsy syndromes (e.g. juvenile absence epilepsy, neonatal seizures, juvenile myoclonic epilepsy). Thus, neuropaediatricians must very often rely on their own medical judgment to select the 'best' treatment option for an individual patient. Physicians look to their colleagues and to expert opinion to help 'fill the gaps' left by randomized clinical trials. The lack of therapeutic guidelines in pediatric epilepsies provided by recognized professional organizations results in attempts to provide physicians with practical information established by expert opinion groups.

Results of expert opinion surveys may reflect many additional variables that are not considered in large randomized trials focused primarily on AED-related aspects, particularly on effectiveness and safety. Expert opinion statements also reflect country-specific variables such as national registration, reimbursement, and insurance coverage.

The first such pediatric survey was completed by a group of 39 specialists in the United States in 2004–2005.[8] The recommendations represented the first use of the expert consensus survey method in the field of pediatric epilepsy. A similar survey was performed in 2007 with a group of 42 Western European pediatric epileptologists.[8]

In the present study we summarize the therapeutic choices of Polish pediatric neurologists in similar clinical situations. It is the first such study from the Central and Eastern European countries. The recommendations resulting from this survey should not be seen as clinical guidelines, but the therapeutic preferences of Polish pediatric neurologists. It provides information on how individual patient variables, labeled indications and Poland-specific reimbursement issues influence decisions on treatment strategies and drug selection.

2. Methods

Polish specialists in pediatric neurology were asked to participate in this survey. The specialists were identified by regional consultants who indicated physicians with substantial expertise in epilepsy therapy. The number of specialists from each region was relative to the number of pediatric neurologists practicing there. No honorarium was provided. The survey was conducted with the support of UCB Pharma.

The survey was developed on the basis of a previously published European survey.[9] It was designed to address key decision/selection points in the management of epilepsy and seizures in pediatric patients in Poland. It should be noted that not all of the drugs listed in the survey questions are fully available or reimbursed in Poland. Some products available in Europe can be imported to Poland on demand. Survey questions were prepared in Polish and also supplemented for emerging AEDs.

There were a total of 35 questions on approximately 650 treatment options for following conditions: symptomatic myoclonic and generalized tonic-clonic seizures (GTCS), complex partial seizures, neonatal seizures, infantile spasms, Lennox-Gastaut syndrome (LGS), febrile seizures, benign childhood epilepsy with centrotemporal spikes (benign rolandic epilepsy; BECTS), absence epilepsy, juvenile myoclonic epilepsy (JME), newly diagnosed epilepsy in the emergency department and status epilepticus (SE).