



An investigation of the characteristics of outpatients with epilepsy and antiepileptic drug utilization in a multicenter cross-sectional study in China

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ABSTRACT

Objectives: This study aimed to describe the distribution of seizure types, clinical characteristics, and antiepileptic drug (AED) utilization in patients with epilepsy visiting tertiary hospitals in China.

Methods: This was an observational, cross-sectional epidemiology study conducted at 11 tertiary hospitals across China from May 2014 to November 2014. A total of 1603 patients, of either sex or any age with confirmed diagnosis of epilepsy, visiting outpatient clinics at tertiary hospitals were screened and enrolled. Demographics, seizure types, frequency, etiologies, comorbidities, and current AED therapy were analyzed using descriptive statistics.

Results: Overall, the majority ($n = 1201$; 74.9%) of patients were adults (16–59 years of age), and the mean (SD) age was 27.5 (15.9) years. A total of 989 (61.7%) patients had partial seizures, and 653 (40.7%) had generalized seizures. The majority experienced monthly ($n = 663$) or yearly ($n = 625$) seizures, with 2.7 seizures/month or 2.9 seizures/year, respectively. The most commonly reported symptomatic etiologies were traumatic brain injury, encephalitis, and stroke, whereas the most common comorbidities were sleep disorder, headache, anxiety, and depression. Overall, monotherapy was used in 54.1% of patients, while 30.6% of patients used dual therapy. The most commonly prescribed monotherapy for patients with partial seizures was oxcarbazepine (25.9%), while that for patients with generalized seizures was valproic acid (38.9%), and the most common AED combination was valproic acid and lamotrigine. Overall, valproic acid was the most commonly prescribed AED as monotherapy and combination therapy.

Conclusion: Findings from this study provide extensive information on clinical characteristics and utilization of AEDs in Chinese patients with epilepsy which may help physicians make well-informed clinical decisions.

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1. Introduction

Epilepsy is a common neurological disorder, characterized by repeated seizures resulting from excessive electrical discharge from brain neurons, and a major health concern affecting around 50 million people worldwide [1]. Nearly 80% of people with epilepsy live in developing countries, of whom around 75% of patients do not receive any treatment [1]. In China, more than 9 million people have epilepsy with 6.5 million active cases, which is increasing yearly with 45,000 new cases [2], with increasing burden on both patients and the country [3,4]. Though the prevalence of epilepsy varies in different parts of

China, the overall prevalence is around 2.89%, and around 40%–50% of patients do not receive necessary treatment [2].

A general approach of epilepsy treatment is to achieve seizure-free status with minimal or no adverse events (AEs) [5]. Antiepileptic drugs (AEDs) are the mainstay of treatment, and the number of available AEDs has increased steadily since 1990s. Antiepileptic drugs like phenobarbital (PB), phenytoin (PHT), carbamazepine (CBZ), valproic acid (VPA), ethosuximide, and benzodiazepines were developed before the 1990s [6]; however, several newer AEDs have been introduced thereafter. The newer agents were tested in patients whose seizures were unresponsive to older AEDs [7], with some advantages in terms of pharmacokinetics, tolerability, and a reduced interaction potential [8,9].

In China, the majority of the epilepsy specialists are associated with tertiary hospitals primarily serving patients with newly diagnosed epilepsy and referral patients; however, there are no national or hospital-based databases to describe the demographic status and treatment pattern of the patients with epilepsy in China. Limited data available [10–15] on epidemiology, clinical characteristics, and treatment patterns of epilepsy patients in China may not be sufficient to describe the current disease and treatment trends supporting development of robust treatment guidelines. This study was conducted to describe the distribution of seizure types, clinical characteristics, and utilization patterns of AEDs in patients with epilepsy who seek consultation at tertiary hospitals in China.

2. Methods

2.1. Study population

Patients of either sex or any age with confirmed diagnosis of epilepsy (according to the International Classification of Epileptic Seizures, 1981) [16] based on available medical records (clinical, electroencephalogram [EEG], and/or neuroimaging findings), who were previously treated, were untreated, or are currently being treated for epilepsy, participated in this study. Patients with current or previous diagnosis of nonepileptic seizures that could be confused with seizures and patients, in the opinion of the investigator, not likely to be reliable, cooperative, and compliant with study procedures were excluded.

The study was conducted in accordance with the International Conference on Harmonization Good Clinical Practices and applicable local regulatory requirements and principles outlined in the Declaration of Helsinki. The independent ethics committee or institutional review board at each study center approved the study protocol. All participants provided written informed consent to participate in the study. Written informed assents were obtained from children who were able to do so, in addition to consent from their parents or legally acceptable representative.

2.2. Study design

This was an observational, cross-sectional, epidemiology study (GSK Clinical Study Register: ID 200713), conducted at 11 tertiary hospitals across China from May 2014 to November 2014. The study aimed to describe patient characteristics and the current situation of epilepsy treatment of patients visiting epilepsy specialists and general neurologists at tertiary hospitals in China. In order to ensure that the selected tertiary hospitals were representative, a listing of all tertiary hospitals with epilepsy clinics in China was first prepared, and then appropriate sites were selected through multistage stratified sampling according to the number of epilepsy clinics per week, the location of the hospital (north, west, east, or south), and the scale of city (city population, power consumption, and gross domestic product). Patients visiting general neurologists and epilepsy specialists (outpatient clinic) were screened and enrolled consecutively. Newly diagnosed epilepsy was defined as epilepsy (two unprovoked seizures more than 24 hours apart) that was diagnosed during the study period.

2.3. Outcome assessment

Collected data about patient characteristics were as follows: demographic characteristics (age, sex, and weight), seizure type (partial, generalized, or unclassified; according to the International League Against Epilepsy [ILAE] classification [Commissions, 1981 and 1989] [16,17]), seizure frequency (in previous year) for patients with uncontrolled seizures, detailed medical history, electroclinical syndrome, epilepsy etiologies (ILAE 1989) [17], comorbidities, prescription patterns of AEDs (monotherapy, dual therapy, triple therapy; older/newer AEDs) excluding Chinese traditional medicines used as AEDs (no AEDs were excluded from the analysis from patients using Chinese medicines), most frequent AEDs as monotherapy and dual combination for partial and generalized epilepsies, and proportion of patients who remained seizure-free (defined as having no seizures for at least 12 months or 3 times the longest pretreatment interseizure interval). Additionally, overall AED utilization (percentage of patients taking individual AEDs and AED combinations), differences in frequency of utilization of individual AEDs between groups (seizure type, sex, and age), comparison of average daily dose of AEDs with 50% of defined daily dosages (DDDs) in patients ≥ 16 years of age, differences in average daily dose of AEDs in seizure-free patients and patients with uncontrolled seizures, and factors influencing the utilization of most commonly prescribed AEDs were also assessed.

2.4. Statistical analysis

For the analysis of demographics and difference in frequency of drug utilization, patients were divided into three age groups as follows: children (< 16 years old), adult (16–59 years old), and elderly (≥ 60 years). Categorical variables were presented using numbers and percentages, whereas continuous variables were summarized using mean, standard deviation, median, and range. The 95% CI was calculated where appropriate. Frequency differences for continuous variables were compared using analysis of variance (ANOVA) or the Wilcoxon signed-rank test, and Pearson's chi-squared test or Fisher's exact test for categorical variables, as appropriate. The average daily dose of each individual AED was calculated and compared with 50% DDD [18] in patients ≥ 16 years of age. Missing data were regarded as missing, and no imputation was implemented. Statistical analysis was performed using SPSS statistical software (version 13.0). Statistical significance was considered if p value was ≤ 0.05 . Because of clustered sampling (hospital as cluster), sensitivity analysis using generalized estimation equation (GEE) was applied to fit the dependent data.

3. Results

3.1. Demographic characteristics

A total of 1603 patients were included in this study, of which the majority ($n = 1201$; 74.9%) belonged to the age group 16–59 years, followed by 318 (19.8%) patients in the age group < 16 years and 84 (5.2%) patients in the age group ≥ 60 years. The mean (SD) age of the 1603 patients was 27.5 (15.9) years, and the mean (SD) weight was 56.2 (16.9) kg. There were more males (54.3%) (Table 1).

3.2. Seizure type and frequency

Overall, 989 (61.7%) patients had partial, 653 (40.7%) had generalized, and 4 (0.2%) had unclassified seizures. Among patients with partial seizures, the majority ($n = 686$; 69.4%) had secondarily generalized seizures, whereas the tonic-clonic type of seizure was most common ($n = 552$; 84.5%) among patients with generalized seizures (Table 1). The majority of patients experienced monthly ($n = 663$) or yearly ($n = 625$) seizures, with 2.7 seizures/month or 2.9 seizures/year, respectively (Table 1). When categorized by partial and generalized seizures, the

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