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Predictors of nonadherence in children and adolescents with epilepsy: A multimethod assessment approach

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ABSTRACT

Background: There is a lack of a standardized tool for adherence measurement in patients with epilepsy. Studies in children with epilepsy have reported adherence in 50–96.5%. The primary objective of this study was to identify predictors of nonadherence to antiepileptic drugs (AEDs) using two different methods in Jordanian children and adolescents with epilepsy.

Methods: Participants included 63 children and adolescents with epilepsy and their primary caregivers. Adherence measures included a subjective approach (using parent and child self-reports via Medication Adherence Report Scale (MARS)) and an objective method (measuring plasma levels of AEDs coupled with the application of population pharmacokinetic models to predict AED concentrations in the children). The Beliefs about Medicines Questionnaire (BMQ) was used to examine the association beliefs about medicines with nonadherence in the participating patients.

Results: Measuring AEDs in plasma samples captured the highest percentage of nonadherence (36.2%). No significant agreement was found between the AED plasma level method and both the MARS (parent) and MARS (child). The overall nonadherence (combined methods) to AED therapy in children with epilepsy was 44.4%. Logistic regression analysis indicated that children with longer duration of disease were more likely (odds ratio [OR]: 1.54, 95% confidence interval [CI]: 1.16–2.04) to be classified as nonadherent as were children whose parents have lower AED Necessity scores (OR: 0.68, 95% CI: 0.53–0.87) and higher AED Concerns (OR: 1.6, 95% CI: 1.26–2.04) as measured by the BMQ.

Conclusion: The use of a multimethod approach for assessing adherence increases sensitivity for detection of nonadherence to AEDs. Disease duration and parental necessity beliefs and concerns assessed by the BMQ-specific questionnaire were significant predictors of nonadherence to the AED therapy. The need for the development and implementation of interventions that can be employed to improve adherence within this pediatric population has been highlighted by the high levels of nonadherence identified.

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1. Introduction

Worldwide, 50 million people have epilepsy [1], and 10.5 million of them are children under 15 years old [2]. Adherence assessment and factors that affect adherence in children with epilepsy are not widely researched [3]. The term of medication adherence can be defined as “the extent to which patients take medication as prescribed by their healthcare providers” [4]. Successful therapy using antiepileptic drugs (AEDs) can eliminate or reduce symptoms; adherence to AEDs is subsequently a key to treatment success [5].

Reports on the extent of nonadherence to AEDs in patients with epilepsy vary considerably, ranging from 3.5% to 68% in children [3, 6, 7] and from 28.9–74.8% in adults [8–11] depending on the population studied and method used to assess adherence.

Generally, there are several factors that can influence medication adherence to AEDs in adolescents including regimen complexity or their beliefs about medication as they may stop taking the medication because they do not want to be viewed as being different than others [12]. Research on children population has revealed that disliking the taste of medication, running out of medications [13], parent forgetfulness, refusal to take medications [13, 14], difficulties in swallowing the medication [14], lower socioeconomic status [15–17] and family conflict and difficulties in communication particularly during adolescence [17]

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were barriers to adherence to AEDs. Poor adherence to prescribed AEDs is associated with negative consequences such as reduced seizure control [18–20], higher incidence of hospital admissions [20–22], and increased healthcare costs [5, 23, 24]. Adherence assessment in children newly diagnosed with epilepsy is critical for clinicians to make accurate treatment decisions such as changing the dose of the drug [25]. In addition, clinicians should take into consideration that White coat adherence may occur at the beginning of the treatment, and therefore, it should be examined to avoid unnecessary changes to medication treatment [26].

Early adherence interventions could change the seizure control, particularly if variability in adherence was minimized primarily after diagnosis [27, 28]. Examples of such interventions include text messaging and application-based interventions to increase adolescent adherence to AEDs [29], supporting treatment adherence regimens [30] and family-tailored adherence intervention targeting nonadherence to AEDs in children with new-onset epilepsy [31].

There is no standardized tool for adherence measurement in patients with epilepsy [32]. Several studies have used the Morisky scale [33] or the Medication Adherence Report Scale (MARS) [3, 34] as self-report measures to assess adherence in patients with epilepsy [18, 35] and the Pediatric Epilepsy Medication Self-Management Questionnaire, which have been validated in adolescents [36] and caregivers of children [37]. Other researchers have assessed adherence using 'pill' counts [38], electronic monitors [6, 39, 40], and medication refills [5, 23, 41, 42].

Adherence assessment using objective methods such as blood-level determination of AEDs has also been utilized in various studies [3, 43–47].

Each adherence assessment method has its advantages and disadvantages [4]. In general, objective methods are more accurate in measuring adherence; however, this approach is expensive and associated with difficulties in terms of developing assays and interpretation of results [4]. Moreover, variability in the pharmacokinetics of the AEDs due to variable absorption, drug interactions with medications taken concomitantly and differences in rates of drug metabolism may influence the results obtained [45]. Utilizing established population pharmacokinetic (PopPK) models of the AEDs for the prediction of concentration of the AED by replacing the covariates in the models with patients' actual values (i.e., time of sampling, age, dose, body weight) minimizes the intra- and interindividual variability associated with the measured concentrations and provides a good approach to accurately assess the blood level of AED [3].

For drugs with short half-lives, taking doses in some cases a few hours before a test raises the drug level reasonably close to target, thus depending on drug concentration measurement as a single method for assessing adherence can be misleading.

Subjective methods, which include asking patients questions about their medication taking behavior (questionnaires), are less accurate measures of adherence; however, they are more convenient and usually less expensive [4].

Adherence is best determined by using different assessment approaches and triangulating the results obtained to provide an overall assessment [45].

Patients' beliefs about their prescribed medicines (BMQ), involves assessment of patients' beliefs about medication prescribed for a particular illness. It also has two major themes, which are 'Necessity Beliefs' and 'Concerns'. Patients' views about the necessity of the medication for maintaining or improving health describe the 'Necessity Beliefs' whereas beliefs about the potential adverse effects of taking medication explain the 'Concerns' [48]. This 'Necessity–Concerns Framework (NCF)' possibly is considered as a useful model for healthcare providers to identify and address key beliefs supporting patients' attitudes and judgments about treatment [49].

The main aim of the present study was to use subjective and objective approaches to assess the level of adherence to prescribed AEDs in children with epilepsy. Additional aim was to identify factors that influence adherence including patients' beliefs about AEDs. It was hypothesized that low scores of the BMQ-necessity subscale and high scores of

the BMQ-concern subscale administered to parents would be associated with poor medication adherence in the recruited children.

2. Methods

2.1. Study design

This cross-sectional study was carried out at the child neurology clinic at Jordan University Hospital (JUH), a tertiary care hospital in Amman, the capital of Jordan. The study was approved by the Research Ethics Committee of the University of Jordan Hospital. The study was carried out between October 2015 and November 2016. Subjective adherence to AEDs was assessed in children with epilepsy using a validated Arabic version of MARS [50] and by measuring AED plasma levels (objective method).

Factors affecting adherence to antiepileptic drugs were determined by using parent necessity and concern subscales of the validated Arabic version of the Beliefs about Medicines Questionnaire (BMQ)-specific [50].

The overall seizure severity of each participating child was assessed by their physician, using the Global Assessment of Severity of Epilepsy (GASE) scale [51].

2.1.1. Study patients and data collection

Children with epilepsy aged ≤ 18 years who were receiving AEDs [including one or more of the following: carbamazepine (CBZ), levetiracetam (LVT), sodium valproate (VPA)] for at least one month were included. After screening of the prescribed medications in the hospital to children with epilepsy, it was noted that those 3 drugs were the most prescribed medications. The inclusion of all antiepileptic drugs would be better; however, due to financial limitations, these 3 drugs were chosen in order to recruit higher percentage of patients.

Parents were asked to sign a consent form after receiving a full explanation of the study, and only children whose parents provided written informed consent were included. Assent was also obtained from children who were considered capable of providing this by their physician.

The medical files were reviewed to collect data on patients' demographics, current medications, and medical history (changes to medications, type of seizures, and disease duration).

2.1.2. Study measures and adherence assessment

The MARS and BMQ-Specific questionnaires were self-completed by parents and their children (if ≥ 11 years old, during the clinic visit). Capability of children to complete the questionnaire was determined by his/her physician.

2.1.3. Medication Adherence Report Scale (MARS)

The validated Arabic translations of the MARS questionnaires (parent and child version) were used [50] to assess adherence to medication in the past month. The child's version consists of five items; mean scores were summed to give a scale score ranging from 1 to 5. The parent's version consists of six questions; mean scores were summed to give a scale score ranging from 1 to 5. The parent MARS questionnaire is the same as the patient/child questionnaire, except for the last item that is not relevant to the child, i.e., "I don't give it because my child refuses it". Higher scores indicate higher levels of self-reported adherence. In the present study, a 90% cut-off point for adherence was used, i.e., a participant was considered to be adherent, if the parental/child MARS score was at least 4.5 out of 5. This cut-off point was used in previously published studies for the assessment of adherence to medication in children [3, 52].

2.1.4. AED concentration in plasma samples

Blood samples (2 ml) were collected from each participating child at a clinic visit (the date that the participants completed the study

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