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Computer-based monitoring and evaluation of epilepsy-related health variables and their impact on treatment decision

Melanie Bergmann [a], Manuela Prieschl [a], Gerald Walser [a], Gerhard Luef [a], Gerhard Rumpold [b], Iris Unterberger [a,*]

[a] Department of Neurology, Innsbruck Medical University, Austria
[b] Department of Medical Psychology, Innsbruck Medical University, Austria

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ABSTRACT

Objective: This study aimed to determine the effectiveness of electronic patient-reported outcomes (ePROs) with focus on epilepsy-specific quality of life, psychiatric and psychosocial burden, drug side effects, and patient satisfaction via the Computer-based Health Evaluation System (CHES) and to evaluate their impact on treatment regimen.
Methods: Forty consecutive patients with drug-resistant focal epilepsy undergoing prolonged video-electroencephalography (EEG) monitoring at the Department of Neurology, Innsbruck Medical University were included and randomized to an intervention group (questionnaire results accessible to the physicians) and a control group (questionnaire results inaccessible to the physicians). Patients had to complete questionnaires on the day of admission (T0) and the day of discharge (T1).
Results: Overall, twenty-five patients (25/40, 62.5%) showed abnormal assessment results, twelve of them exclusively due to pathological scores on the Liverpool Adverse Events Profile (LAEP). Mean LAEP score was within the pathological range of 48.8 points (48.8 ± 7.2). The psychosocial burden with respect to the Performance, Socio-Demographic Aspects, Subjective Evaluation (PESOS) scale "fear" (48.7 ± 21.4) was also moderately affected. Moreover, mean anxiety (9.1 ± 4.4) and depression (7.6 ± 4.5) scores were both slightly abnormal. Quality of life (as measured using the Quality of Life Inventory in Epilepsy (QOLIE-31)) was moderately impaired (seizure worry: 46.5 ± 21.3, overall quality of life: 52.6 ± 18.6, well-being: 54.1 ± 16.3, energy–fatigue: 39.4 ± 14.7, cognitive functioning: 41.4 ± 19.5, medication effects: 46.2 ± 23.4, social functioning: 51.1 ± 20.8, and total score: 47.2 ± 12.3). Careful medical history-taking and patient–physician consultations alone failed to detect needs for psychological/psychiatric help in three out of 7 patients in the control group (42.8%). Changes over time in Hospital Anxiety and Depression Scale (HADS) and QOLIE-31 scores were not significant.
Conclusion: The use of ePROs was feasible and well accepted in the clinical setting. Treatment-associated adverse effects were the most frequently reported health-related restrictions. In particular, psychometric evaluation by applying ePROs can detect health-related problems in patients with epilepsy.

1. Introduction

Epilepsy is one of the most common neurological diseases with a prevalence ranging from 5 to 9 per 1000 persons [1–3]. Studies focusing on seizure-free and nonseizure-free patients have shown that seizure freedom is the determining factor involved in a satisfactory quality of life [4–6]. As for seizure-free patients, it is assumed that their quality of life is comparable with that of the general population [7,8]. In addition, patients with epilepsy are subject to a higher risk of depressive or anxiety disorders [9]. In population studies, the frequency of anxiety and depression was as high as 30% [10]. Again, both disorders have a negative impact on quality of life [11,12]. Health-related items are typically assessed by means of self-reported measures (i.e., by the patients themselves) and are known as patient-reported outcomes (PROs) [13]. Such information is obtained to an increasing extent via electronic assessment, which provides direct feedback at a low administrative expense [14]. Furthermore, use of electronic PROs (ePROs) can significantly reduce the problem of missing data [15]. Prior studies have shown that electronic and paper–pencil PROs delivered equivalent measures [16–18]. Moreover, as PROs can provide immediate feedback to the treating physician, improvement in health-related quality of life could be better demonstrated compared with scenarios where quality-of-life measurements are not used [19]. In an outpatient setting, a systematic screening for antiepileptic drug (AED) side effects

* Corresponding author at: Department of Neurology, Medical University Innsbruck, Anichstrasse 35, A-6020 Innsbruck, Austria.
E-mail address: iris.unterberger@tirol-kliniken.at (I. Unterberger).

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increased the identification of toxicity and guided medication changes to reduce adverse effects [20].

In this light, we aimed to electronically assess epilepsy-specific quality of life (using the Quality of Life Inventory in Epilepsy (QOLIE-31)), psychosocial and psychiatric burden (using the Performance, Socio-Demographic Aspects, Subjective Evaluation (PESOS) and Hospital Anxiety and Depression Scale (HADS), respectively), drug side effects (using the Liverpool Adverse Events Profile (LAEP)), and patient satisfaction (using the Patient Satisfaction Questionnaire (ZUF-8)) in patients with drug-resistant focal epilepsy. Furthermore, we wanted to examine the impact of provided questionnaire results on treatment decision.

2. Methods

2.1. Patients

We prospectively included forty adult (≥18 years) patients with drug-resistant focal epilepsy who underwent a scheduled prolonged video-electroencephalography (EEG) monitoring at the Department of Neurology, Innsbruck Medical University. Patients were eligible for the study if they could read and understand the German language and were able to complete all questionnaires on their own. On the day of admission (T0), demographic and epilepsy-related parameters were collected. On this view, a systematic approach regarding careful medical history-taking was performed, including the following factors: gender, age at examination, age at epilepsy onset, seizure classification, seizure frequency, etiology, current AED treatment, living status, and comorbidities. Moreover, frequent patient–physician consultations allowed for better identification of patients' needs. Patients were asked to fill in computer-assisted questionnaires concerning epilepsy-specific quality of life (QOLIE-31), epilepsy-related restrictions in daily life (PESOS), psychiatric burden (HADS), and side effects of AEDs (LAEP). On the day of discharge (T1), patients again completed QOLIE-31 and HADS questionnaires and filled in an additional questionnaire about patient satisfaction (ZUF-8).

2.2. Study design

Patients were randomized into two groups: the first group consisted of patients whose questionnaire results were accessible to the treating physicians (i.e., intervention group). In case of pathological QOLIE-31, HADS, and PESOS scores, the physicians were instructed to organize psychological/psychiatric consultation; in case of abnormal LAEP scores, they were told to adjust the AED regimen. Conversely, physicians were blinded to the questionnaire results in the second group of patients (i.e., control group). In these cases, any further interventions were dependent on the results of medical history-taking alone. Our main interest was to examine the impact of different questionnaires in detecting patient needs. All treating physicians were staff neurologists at the Department of Neurology, Innsbruck Medical University and received instructions in handling the computer software (Computer-based Health Evaluation System, CHES) [21] as well as in dealing with the results. The questionnaire results were available to the physicians via CHES [21] on T0 and T1 immediately after patients filled in the ePROS. Ethical committee approval was obtained at Innsbruck Medical University. All patients granted written informed consent according to the Declaration of Helsinki.

2.3. Assessment of the questionnaires

2.3.1. CHES

The CHES is software for electronic patient-reported outcome monitoring and serves routine registration and processing of medical and psychosocial patient data (e.g., disease-specific quality-of-life data, psychiatric burden) [21].

The data were stored on a device and processed using the software on a computer to produce graphic diagrams for the doctor–patient discussion.

2.4. Applied questionnaires

2.4.1. QOLIE-31

The QOLIE-31 is a 31-item quality-of-life questionnaire comprising seven subscales covering general and epilepsy-specific domains. Its subscales are divided into two factors: emotional/psychological and medication/social effects. The present study calculated the total score and the seven subscores. The maximum total score is 100. A higher total score is associated with a better quality of life [22,23].

Mean values of the QOLIE-31 subscales, dependent on seizure frequency, were published by May et al. [23]. They assessed the psychometric properties of the German translation of the QOLIE-31 in 509 patients with epilepsy who were admitted to the Epilepsy Center Bethel [23].

2.4.2. PESOS

The structure of PESOS includes the following subgroups: demographic data, medical data, performing activities of daily living (mobility, social contacts, participating in social life, leisure activities), quality of life (epilepsy-related impairments in daily life, epilepsy-specific anxiety, stigma, emotional adaptation), and modules for special patient groups (problems at work, problems at school, problems with parents) [24].

2.4.3. LAEP

The LAEP is used for quantitative registration of side effects (unsteadiness, tiredness, restlessness, anger/aggression, nervousness, headache, hair loss, problems with skin, double vision, upset stomach, difficulty in concentrating, trouble with mouth and gums, shaky hands, weight gain, dizziness, sleepiness, depression, memory problems, disturbed sleep) experienced by patients with epilepsy under antiepileptic therapy in the preceding four weeks since a change in therapy. Scores of ≥44 indicate clinically relevant side effects [20,25].

2.4.4. ZUF-8

The ZUF-8 is an instrument that registers a patient's overall satisfaction with his/her medical treatment. More than eight items address general satisfaction, including aspects of the clinic and the treatment received by the patient. The cutoff value in somatic settings for high patient satisfaction is ≥24 points [26].

2.4.5. HADS

The target parameters of HADS are anxiety and depression [27]. Cases can be identified on the basis of described cutoff values. Scores of seven or less indicate healthy patients. Scores between eight and ten are classified as borderline cases. A score of eleven or above notifies possible clinically relevant cases of anxiety and depression and therefore needs further medical evaluation. Validation of the German version is primarily based on a random sample of 6200 patients with cardiac and other internal or psychiatric diseases as well as controls [28].

2.5. Statistical analysis

Descriptive data were analyzed using the statistics software IBM SPSS, version 24 for Windows. Patient characteristics and questionnaire results are presented as means, standard deviations (SDs), and medians. Normal distribution was assessed with the Kolmogorov–Smirnov test. Comparison between the intervention group and the control group regarding medical treatment decisions (psychiatric/psychological help or no intervention) was performed using chi-square test. In case of a normal distribution, t-test was used to test group differences (intervention group/control group, left-, right-, or bilateral-sided

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