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Validation of the side effect and life satisfaction (SEALS) inventory

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Diminished quality of life (QOL) is a common feature of epilepsy. It is generally more severe among patients with poor seizure control but prevalent, to a clinically significant degree, even among those whose seizures are well controlled. People with epilepsy frequently report diminished socialization, negative self image, feelings of stigmatization, reduced earnings potential, and diminished hope and ambition. Problems with antiepileptic drug (AED) therapy are common, and AED therapy is recognized as an important determinant of health-related quality of life (HRQOL). A clinically efficient psychometric instrument is needed to measure its impact. The Side Effect and Life Satisfaction (SEALS) inventory is a 38-item, patient-completed questionnaire designed to measure satisfaction with AED therapy. We tested its construct validity in comparison with three widely used psychometric instruments of similar design, the Profile of Mood States (POMS), the Hospital Anxiety and Depression (HAD) scale, and the Medical Outcomes Study-Cognitive Functioning (MOS-COG) scale.

All four instruments were completed by 307 epilepsy patients. A matrix of Pearson's correlations was produced for the SEALS inventory and the comparative instruments. A statistically significant correlation was found for each planned comparison. We conclude that the SEALS inventory is a valid psychometric instrument, well suited for use in clinical investigations of AED therapy and in the practical, long-term management of epilepsy.

Key words: epilepsy; psychometric instrument; validity; health-related quality of life; side effect and life satisfaction inventory.

INTRODUCTION

There is ample evidence that many people with epilepsy also suffer a clinically significant deficit in health-related quality of life (HRQOL)[1–3], both in terms of symptoms resulting directly from the condition, and loss of psychosocial functioning consequent upon these symptoms. The psychosocial injury of epilepsy is more severe among patients with poor seizure control, but prevalent, to a clinically significant degree, even among patients whose seizures are reasonably well controlled[1,2]. Baker *et al.*[1] surveyed 5211 members of epilepsy support groups and outpatient clinics in 15 European countries—a study population acknowledged to contain a disproportionately high number of people with epilepsy of greater than average severity. Many respondents said epilepsy had negatively affected their plans and ambitions (47%), social life (41%), and feelings about themselves (40%). Thirty-eight percent said epilepsy had diminished their ability to work and their standard of living. In a smaller survey[2] of 696 patients selected by protocol ($\geq$1 seizure in the past 2 years or seizure-free on continuing AED therapy) from the records of 31 UK general practitioners, 44% of patients answered 'a lot' or 'some' when asked if epilepsy had limited the kind of work they could do. Other aspects of life reported to be similarly affected included relationships with friends (37%), feelings of self (37%), plans and ambitions (35%), social activities (32%), and ability to work (29%).

Aside from its anticonvulsant effects, AED therapy is an important medical factor influencing HRQOL. Not only is drug therapy a daily reminder to the patient of his or her condition, it can also exert a strong negative influence in the form of unwanted side effects, particularly cognitive and neurological impairment[4]. Baker *et al.*[1] reported that 88% of 96% of 5211 re-

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spondents on AEDs experienced at least one neurological AED side effect in the month prior to the survey. The most common were tiredness (58%), memory problems (50%), difficulty concentrating (48%), sleepiness (45%), difficulty thinking clearly (40%), and nervousness and agitation (36%). Forty-four percent said they worried 'a lot' or 'some' about the possible side effects of AED therapy, and 31% had changed AEDs at least once in the past year because of side effects. Patients in the UK-generalists study[2] reported AED side effects 'always a problem' or 'sometimes a problem' as follows: tiredness (41%), memory problems (33%), difficulty concentrating (30%), sleepiness (28%), nervousness/agitation and headache (26%, each), depression (25%), disturbed sleep (24%), restlessness (21%), and feelings of aggression (19%).

To better understand the component role of AED therapy in HRQOL and to determine whether the psychosocial injury of epilepsy can be ameliorated without compromising the primary therapeutic goal of optimum seizure control, researchers and practitioners need a reliable, validated, clinically efficient psychometric instrument to measure patient satisfaction with AED therapy. In 1982, Brown and Tomlinson[5] described the development of a patient-completed questionnaire to assess the psychosocial effects of AED therapy, termed the Side Effect and Life Satisfaction (SEALS) inventory, using a patient population to generate key symptoms. The goal was to construct an instrument to distinguish not just drug effects from disease effects, but also to distinguish the psychosocial effects of one antiepileptic drug from those of another in comparative clinical trials. To be useful in such studies, the questionnaire had to be practical for repeated use, i.e. simple to understand and not excessively time consuming. It also had to be sensitive to small changes in the patient's HRQOL over time. The final version comprised 50 questions scored on a four-point Likert scale and grouped by five subscales or 'factors': fatigue; satisfaction; interpersonal relations; mood and irritability; and general cognitive difficulties.

Gillham *et al.*[6] studied and modified the Brown–Tomlinson SEALS to produce the refining of the five factors and reducing the number of questions to 38, using principal components analysis. The twelve discarded questions did not load significantly on any one factor; they tended to be items confounded by factors not necessarily related to the patient's epilepsy, such as marital status, or personal preferences. Gillham and associates also showed that the five SEALS factors were sensitive to differences between treatment groups and to changes in treatment, findings that suggest the SEALS inventory would be useful to assess patient satisfaction with anticonvulsant therapy.

The present study was undertaken to test the construct validity of the SEALS inventory, using for comparison three well-validated instruments similar to the SEALS inventory or one of its five factors: the Profile of Mood States (POMS)[7], the Hospital Anxiety and Depression (HAD) scale[8], and the Medical Outcomes Study-Cognitive Functioning (MOS-COG) scale[9].

MATERIALS AND METHODS

Approval from the local Ethics Committee was sought and obtained at two sites; (Glasgow and Dundee), at the third, (Liverpool), completion of the questionnaires was deemed a normal part of clinical practice, obviating Committee approval.

Patients and data collection

Enrollment was open to men and women 18 years of age or older with epilepsy diagnosed by a consultant neurologist. Newly diagnosed patients and patients still undergoing investigation were excluded, as were those who lacked the ability to read, comprehend, and complete the SEALS inventory and comparative instruments without assistance (12 patients). Demographic data and information on disease characteristics were gathered by clinic personnel through direct interview and from clinic records.

Consecutively presenting patients at three clinics were invited to participate in the study. Each prospective patient received written and oral instruction regarding the nature and purpose of the study. Consent was inferred from the informed patient's willingness to participate, and was virtually 100% amongst those patients who did not have further appointments imposing time constraints. Refusal to participate in one centre (Liverpool $n = 100$) was not recorded, but in the other two centres was less than 1%. Participation entailed completing the SEALS inventory and the three comparative instruments. Written and oral instructions for each instrument were provided, but once the patient began, no further assistance was available except staff's encouragement to carefully reread the written instructions. Questionnaires were completed in the clinic, in a side room, before the patient's routine appointment. There was no time limit, implied or prescribed, for completion of the SEALS inventory or the other instruments, and the average time to complete was 45 minutes.

Psychometric instruments and validation strategy

The SEALS inventory contains 38 questions related to the patient's feelings and behaviour over the past