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Brief Communication

Psychometric properties of the Polish version of the Hamilton Anxiety Rating Scale in patients with epilepsy with and without comorbid anxiety disorder

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ABSTRACT

Objective: Anxiety disorders (ADs) are frequent comorbid disorder in patients with epilepsy (PWE). The availability of validated screening instruments to detect AD in PWE is limited. The aim of the present study was to validate the Polish version of the Hamilton Anxiety Rating Scale (HARS) in adult PWE for the detection of AD.
Methods: A total of 96 outpatient PWE completed the self-report symptom scale, the HARS, and were diagnosed with the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision (DSM-IV-TR) Axis I disorders (SCID-I). The sensitivity, specificity, positive and negative predictive value, and receiver operating characteristic (ROC) curves were assessed to determine the optimal threshold scores for the HARS.
Results: Receiver operating characteristic analyses showed areas under the curve at 81.2%. For diagnoses of AD, the HARS demonstrated the best psychometric properties for a cutoff score ≥17 with sensitivity of 68.8%, specificity of 87.5%, positive predictive value of 52.4%, and negative predictive value of 93.3%.
Conclusions: The Polish version of the HARS performed moderately well as a screening instrument for ADs in PWE. In the epilepsy setting, the HARS maintains moderate sensitivity, high specificity, and excellent Negative perdictive value (NPV) but low Positive perdictive value (PPV) for diagnosing ADs with an optimum cutoff score ≥17. These results suggest that the HARS performed better to rule out anxiety, however, because of moderate sensitivity, some cases of anxiety might be missed.

1. Introduction

Anxiety disorders (ADs) are common psychiatric comorbidity in epilepsy, affecting a proportion of patients, and the incidence for ADs is substantially higher in people with epilepsy as compared with the general population [1,2]. The presence of comorbid ADs in PWE is associated with poorer quality of life and increased healthcare utilization, and also may affect medical outcomes, such as poorer seizure control and increased side effects associated with antiepileptic medication [3].

The Hamilton Rating Scale for Anxiety (HARS) is a widely used clinician-administered measure of anxiety [4]. The HARS was one of the first rating scales developed to measure the severity of anxiety symptoms and is still widely used today in both clinical and research settings as the reliable and valid interviewer-administered instruments assessing the severity of anxiety. It has become the standard in the field to provide an indication of anxiety severity and as a guide to evaluate recovery in the general population. The scale consists of 14 items, each defined by a series of symptoms, and measures both psychic anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety) [4].

The detection of AD is of vital clinical importance in patients with epilepsy (PWE). Still, the measures of severity are also to be assessed against the population-specific criteria. Several factors including antiepileptic drugs (AEDs) side effects as well as atypical symptomatology may affect the accuracy of psychiatric diagnosis in PWE. In particular, screening instruments lacking reference to standardized structured psychiatric interview may not produce credible diagnosis, as tools used in the general population may not be valid and reliable in PWE [5]. Therefore, the definition of PWE specific cutoff scores is of prime importance.

A psychometric instrument may exhibit substantial variability for the targeted population. Thus, with limited data and some conflicting results, there is a need for validation studies against the golden standard, such as standardized structured psychiatric interviews, in order to produce conclusive cutoff with valid diagnosis points for specific psychometric screening instruments that are optimized for PWE. To date, in PWE formally diagnosed with comorbid AD, there was no such data available in literature with regard to the HARS being rater-

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based psychometric scale. The present study explored psychometric properties of the HARS in a sample of PWE with and without comorbid AD, in the interest of providing clinicians with reliable normative values.

The aim of this study was to validate the psychometric properties of the Polish version of the HARS in PWE in order to determine its optimal specificity, sensitivity, and cutoff scores for identifying ADs as defined by diagnostic interview.

2. Methods

2.1. Study population

This study used data collected as part of a larger study reported elsewhere [2]. Briefly, 118 consecutive PWE from a tertiary epilepsy center were screened, with 96 patients enrolled. Subjects who received a diagnosis of active epilepsy according to the International League Against Epilepsy criteria [6] receiving stable antiepileptic treatment in the past 2 months aged 18–65 years were included. The exclusion criteria selected to reduce the impact of periictal and ictal psychiatric symptoms were last seizure within 24 h of examination and more than 10 seizures in the last month. Exclusion criteria also included history of severe traumatic brain injury with midline shift as determined with neuroimaging, neurosurgery, unstable disease, or serious neurological disorder. Further exclusion criteria were the identification of psychogenic nonepileptic seizures (pseudoseizures), mental retardation, alcohol and/or drug dependence or abuse in the past 6 months and borderline, antisocial personality disorder as determined by psychiatric interview, as the psychiatric symptomatology manifested in those psychopathologic domains may confound estimates of morbidity rates across ADs.

The study was performed in agreement with the Declaration of Helsinki following the approval of the Ethic Research Committee of the Institution. For each study participant, written informed consent was obtained.

2.2. Evaluation

All subjects were assessed at a single study visit by the same investigator (MSW) and diagnosed with the Structured Clinical Interview for DSM-IV-TR Axis I Disorders (SCID-I) [7]. The structured interview was used to obtain information on disease history and sociodemographic status of patients, including gender, age, economic situation, marital status, the age at seizure onset, duration of epilepsy, seizure frequency, seizure type, experience of auras and duration of treatment, existence of lesions, and psychiatric history. Computed tomography/magnetic resonance imaging, electroencephalogram, and laboratory tests results were available for the majority of subjects. Data were corroborated with referral source records from the epileptologist.

The HARS is a rater-administered tool and consists of 14 items, each defined by a series of symptoms that are rated from 0 to 4 with general guidelines provided for distinguishing the gradations of severity (0 = absent, no symptoms; 1 = mild, occurs irregularly and for short periods of time; 2 = moderate, occurs more constantly and of longer duration, requiring considerable effort on the part of patient to cope with it; 3 = severe, continuous and dominates patient's life; 4 = very severe, incapacitating) [4,8]. The HARS measures both psychic anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety) rather than specific, single, symptoms. It has been predetermined that the results of the evaluation can be interpreted as follows. A score of 17 or less indicates mild anxiety severity. A score from 18 to 24 indicates mild to moderate anxiety severity. Lastly, a score of 25 to 30 indicates a moderate to severe anxiety severity [4]. For analyses, patients were assigned to a comprehensive diagnostic group of ADs including subjects with panic disorder (PD), generalized anxiety disorder (GAD), and agoraphobia. The HARS was administered by the trained rater (MSW).

Table 1
Demographic and clinical characteristics of study population. (Modified from: [1]).

	N = 96 (%)
Male sex (%)	31 (32.3)
Age, in years (SD)	36.6 (12.0)
Age at seizure onset (SD)	19.5 (11.6)
Duration of epilepsy (SD)	17.0 (11.8)
Number of seizures/last month — median (IQR)	3 (2.5)
Seizure type (%)	
Generalized	15 (15.6)
Simple partial	7 (7.3)
Complex partial	27 (28.1)
Partial evolving to general	47 (49.0)
Tonic–clonic	10 (10.4)
Absence	2 (1.0)
Myoclonic	1(1.0)
Atonic	2 (2.1)
Number of AEDs (IQR)	2 (1.2)

SD — standard deviation.
IQR — interquartile range.

2.3. Statistics

In order to determine the diagnostic sensitivity and specificity of the HARS for the DSM-IV AD diagnoses and determine an optimal cutoff point, a receiver operating characteristic (ROC) curve was obtained for HARS. Area under the curve (AUC) values were interpreted according to the following guidelines: 0.9–1, excellent; 0.8–0.9, good; 0.7–0.8, fair; and 0.6–0.7, poor. Cutoff values were established with the (0, 1) minimum distance method giving equal weight to sensitivity and specificity. There were no missing data or outliers.

Frequencies and descriptive statistics were analyzed for each variable. Comparisons between patients with current AD and patients without AD were made using Student's t-tests for normally distributed continuous data, Mann–Whitney's U-test for nonnormally distributed data, and Fisher's exact test for categorical data. To explore the influence of factors on the occurrence of AD, the logistic regression model was used. A value of $p < 0.05$ was considered statistically significant.

3. Results

The study group characteristics are presented in Table 1 with detailed analysis of demographic and clinical variables described elsewhere [1]. According to the SCID-I, the diagnosis of any AD was established in 16 (16.7%) patients. Thirteen (13.5%) PWE met criteria for PD; GAD was found in two patients, and agoraphobia in one subject. Eight subjects with PD had comorbid major depression. Subjects with ADs were older ($p = 0.038$) with no significant differences found with regard to gender, education, partnership, or educational status. The AEDs used in the study group were carbamazepine (CRB, 34.2%), sodium valproate (VAL, 21%), lamotrigine (LTG, 15.7%), and topiramate (TPM, 8.5%).

The mean HARS total score for study groups is shown in Table 2. All HARS scores were significantly higher in PWE with comorbid AD as compared with PWE subjects without AD.

Table 2
Psychometric characteristic of analyzed group.

Rating scale	Anxiety disorders (+) N = 16 Median (IQR)	Anxiety disorders (−) N = 80 Median (IQR)	Mann–Whitney Z	p	Difference (95% confidence interval (CI))
HARS	19 (10.5; 30.5)	3 (1; 11)	3.9177	0.00004	15 (8 to19)

Table 3
ROC analysis of the psychometric scales (presence of the anxiety disorders).

Rating scale	AUC	95% CI	SE	p
HARS	0.8117	0.6688–0.9546	0.071	0.0000

Receiver operating characteristic values for the HARS are shown in Table 3. For diagnoses of AD, the HARS demonstrated the best psychometric properties for a cutoff score of 17 with sensitivity of 68.8%, specificity of 87.5%, AUC of 81.2% (Fig. 1), positive predictive value of 52.4%, and negative predictive value of 93.3% (Table 4).

4. Discussion

In this study, the HARS performed moderately well as a screening tool for detecting ADs in PWE using SCID-I as gold standard. For AD diagnoses, the cutoff score of 17 classified the optimum balance among sensitivity and specificity.

The HARS was intended to rate severity of anxiety symptoms in patients diagnosed with ADs, and cutoff scores have been reported to denote levels of symptom severity. In the assessment of anxiety symptoms in PWE, most studies focus only on patient-reported outcome measures such as Hospital Anxiety Depression Scale anxiety subscale (HADS-A) and Generalized Anxiety Disorder 7-item (GAD-7) scale that were also validated for use in this population [9,10]. However, for clinician-rated scales such as the HARS, there are no validation studies available to our best knowledge. In fact, in the population with epilepsy, the HARS was used primarily as a descriptive tool.

According to one study, 38.8% of PWE experienced significant anxiety symptoms as defined by a rating ≥18 points of the HARS [11]. Using structured clinical interview (MINI-PLUS) and the HARS, de Oliveira et al. [12] found that ADs were present in 42.5% of the study group with the mean HARS score of 14.4 (SD 9.2, $p = 0.012$). As reported by another study, total scores for the HARS were found to be significantly increased in PWE compared with healthy controls (17.12 ± 10.49 vs. 7.82 ± 7.7, $p = 0.0001$) [13]. The aim of a study performed on outpatients with epilepsy was to compare the frequency of anxiety symptoms between patients with frontal lobe epilepsy (FLE) and generalized epilepsy (GE) using the HARS and the HADS scales [14]. In the group with GE, 17.9% of patients scored above the cutoff (14 cutoff point was adopted for this study) of the HARS; the corresponding figure in the group with FLE was 25.0%. Compared with the group with GE, the group with FLE had a significantly higher HARS (10.9 ± 8.7 vs. 7.9 ± 6.8, $p = 0.039$) and HADS total scores. The HARS, HADS subscales, and HADS total scores were all highly correlated with each other; the correlations ranged from 0.468 to 0.885 ($p < 0.001$). In another study on the same population, patients completed among others: the HARS, the HADS, and Quality of Life in Epilepsy Inventory-31 (QOLIE-31) [15]. The HADS anxiety subscale score correlated with the QOLIE-31 overall score, but the HARS score did not. Interestingly, this discrepancy is in line with our observations related to the HARS and the HADS-A performance as a screening measure for AD in PWE.

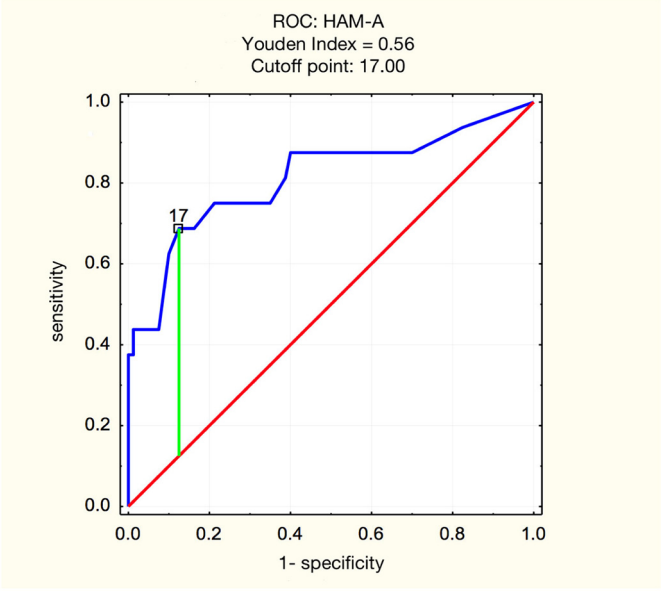

Fig. 1. ROC curve analysis: patients with anxiety disorders vs. patients without anxiety disorders.

Table 4
ROC analysis of the psychometric scales (Cutoff score).

Rating scale	Cutoff score	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
HARS	17	68.8% (41.3–89.0)	87.5 (78.2–93.8)	52.4 (29.8–74.3)	93.3% (85.1–97.8)

Of note, since the validation of Polish HADS-A on the same study sample was published before [9], it is clinically relevant to discuss and compare its results with the HARS validation data, as both scales measure anxiety but require different approach (self-rated vs. observer-rated) and time of administration (2–5 min vs. 10–15 min) information about their performance in PWE could be of great value for a busy clinician trying to decide on which screening tool to use. In this study, the HADS-A performed well as a screening instrument for ADs when using cutoffs ≥10 with sensitivity of 81.3% and specificity of 70.0%, PPV of 31.5%, and NPV of 94.9% [9]. Interestingly, HADS-A showed higher sensitivity than the HARS, which was somewhat not expected. Ideally, both assessment approaches should give comparable results.

The HADS was designed in a way to avoid somatic items [16] that may help minimize the risk of false positives in PWE. In contrast, half of the items on the HARS assess somatic symptoms of anxiety [17], which makes it sometimes difficult to determine if the ratings reflect symptoms of anxiety or side effects of common epilepsy medication [18,19]. Moreover, some AEDs (i.e., LTG, felbamate, and levetiracetam) can aggravate psychic anxiety symptomatology [18,20]. Although in this study sample, no correlation was found related to AEDs and AD; the results of some studies showed significant correlation between anxiety symptoms and the number of currently taken AEDs [14]. Lastly, each HADS-A question concentrates on the evaluation of one symptom whereas each of the items on the HARS scale includes multiple symptoms.

In the present study, a cutoff score for AD was 17, which is similar to the established threshold for the general population (18 points). This recommended cutoff could suggest that the HARS constructs validity, which initially was developed for the use in the general population, and is also adequate for PWE. According to the study results, the HARS maintains, in the epilepsy setting, a moderate sensitivity and a fairly low positive predictive value. The moderate performance of the HARS scale on sensitivity puts in question its use in clinical practice, which prioritizes high sensitivity of screening tools to ensure that real cases are not missed. However, with this purpose in mind, the HADS-A performs better as a quick screening tool to rule in possible AD. Still, in contrast to moderate specificity and low PPV of HADS-A, high specificity and an excellent NPV of the HARS make it a good choice for the purpose of ruling out anxiety. In other words, our results suggest that the HARS is very good at reassuring that disorder is not present, and the scale correctly identified 87.5% of those who do not have AD.

Despite the flaws, the HARS is still widely used for assessing anxiety in the general population. However, its validation data in somatic and neurological disorders are sparse. One of the exceptions is Parkinson disease for which validation studies were done [21]. Leentjens et al. [22] evaluated the discriminant validity of the HARS in patients with Parkinson disease and found optimal cutoff score of 12/13 for diagnoses

of AD according to the DSM-IV criteria. The psychometric properties of the HARS, including its validity as a screening instrument in patients with Parkinson disease already diagnosed with GAD, were investigated by Kummer et al. [23]. The cutoff score was found to be 10/11, with a moderate area under the ROC curve (AUC) of 0.77.

Although the HARS assesses a range of symptoms that are frequent in all of the DSM-IV ADs, the scale has been regarded as most appropriate for GAD [24]. Since in the present study, the majority of participants with AD suffered from PD, the presumed difference in impact of PD or GAD on the scale performance in PWE needs further investigation. In epilepsy, symptoms such as fear are part of the seizure itself, and anxiety often accompanies aura of epilepsy attack. Thus, for individuals with epilepsy, the physiological and cognitive symptoms of epilepsy could be indistinguishable from panic attacks [25–27]. Therefore, in this regard, the advantage of observer-rated scale is that it allows more objective clinician-based evaluation of anxiety symptoms in PWE. Rater-based psychometric instruments are generally thought to be accurate, reliable, and reproducible. They are also more flexible considering the situation-specific and individual aspects of anxiety symptoms. With this in mind, the HARS still may deliver helpful and unique information about anxiety symptoms in PWE and therefore, deserves further investigations.

5. Study limitations

The key study limitation is the small sample size of population and selection bias with regard to the tertiary reference center being associated with a risk of complicated course of epilepsy. The cross-sectional study design and small sample size of the population could have affected the results. Moreover, because of the small sample size, the analysis was performed in all subjects with ADs regardless of the type of disorder and including those with comorbid major depression. As the study procedures occurred during a single visit at the interview site and were completed by the same rater, no test–retest reliability measure for the test results' consistency was performed. Thus, the observations may be biased, and no conclusions may be drawn regarding the stability and reliability of the instrument over time. In order to minimize the influence of periictal and ictal psychiatric symptoms, subjects experiencing more than 10 seizures in the last month before participation were excluded. Therefore, the relatively low anxiety rates for a tertiary clinic population may reflect this exclusion criteria as patients with frequent seizures would generally be expected to have higher anxiety levels. Furthermore, none of the study subjects had a history of epilepsy surgery. Thus, the results cannot be generalized to the entire population of PWE.

Another important study limitation is psychiatric assessment with SCID-I for DSM-IV-TR, which is now updated to version 5 (SCID-5-CV for DSM-5) [28,29]. The usage of outdated instrument could affect the diagnosis rates and the resulting predictive values. However, as for ADs category in DSM-5, aside from the removal of obsessive–compulsive disorder and Posttraumatic stress disorder (PTSD) into separate categories, not much has changed. Agoraphobia and PD have been decoupled and now form two distinct disorders. Additionally, a panic attack specifier is now applicable to any diagnostic category. Apart from that, two disorders (separation anxiety and selective mutism) were moved to this category, and for agoraphobia, specific phobia, and social anxiety disorder (social phobia), the symptoms must last at least 6 months for all ages now. In a recent study, the HARS proved to be still a valid measure of anxiety severity compared with DSM-5 Anxious Distress Specifier Interview (DADSI) [30]. In summary, taking into account the AD diagnoses profile in the study sample, we assume that this would not have a huge impact on the study results.

6. Conclusions

The Polish version of the HARS performed moderately well as a psychometric instrument in terms of screening for ADs in PWE. In the epilepsy setting, HARS maintains moderate sensitivity, high specificity, and high NPV but low PPV for diagnosing ADs, with an optimum cutoff score of ≥17. These results suggest that the HARS can be used to rule out anxiety. However, because of moderate sensitivity, some cases of anxiety might be missed, which calls into question its usefulness as a screening tool in PWE. Future studies should investigate its psychometric proprieties in order to clarify the scale status as a screening tool.

Disclosure of conflicts of interest

No conflicts of interest exist.

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