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A study of the validity and the reliability of the Geriatric Anxiety Inventory in screening for anxiety after stroke in older inpatients

Running title: The Geriatric Anxiety Inventory in screening for anxiety after stroke

Ian I Kneebone [1, 2], Chris Fife-Schaw [3], Nadina B Lincoln [4] and Helena Harder [2, 5]

1. University of Technology Sydney, Graduate School of Health, Discipline of Clinical Psychology, Australia
2. Virgin Care, Department of Psychology, UK
3. University of Surrey, School of Psychology, UK
4. University of Nottingham, School of Medicine, UK
5. University of Sussex, Sussex Health Outcomes Research & Education in Cancer, UK

Address for correspondence:

Professor Ian Kneebone
Head of Discipline (Clinical Psychology)
University of Technology Sydney,
Graduate School of Health
PO Box 123
Broadway NSW 2007
Australia
ian.kneebone@uts.edu.au

Abstract

Objectives: To investigate the validity and reliability of the Geriatric Anxiety Inventory in screening for anxiety in older inpatients post-stroke.

Design: Longitudinal

Subjects: A total of 81 inpatients with stroke aged 65 years or older were recruited at four centres in England.

Main measures: At phase 1 the Geriatric Anxiety Inventory and the Hospital Anxiety and Depression Scale were administered and then the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders 4th edition (phase 2). The Geriatric Anxiety Inventory was repeated a median of seven days later (phase 3).

Results: Internal reliability of the Geriatric Anxiety Inventory was high ($\alpha = 0.95$) and test-retest reliability acceptable ($\tau_B = 0.53$). Construct validity of the Geriatric Anxiety Inventory was evident with respect to the Hospital Anxiety and Depression Scale -Anxiety subscale ($\tau_B = 0.61$). At a cut off of 6/7, the sensitivity of the Geriatric Anxiety Inventory was 0.88 and specificity 0.84, with respect to Structured Clinical Interview diagnosis of anxiety. Hospital Anxiety and Depression Scale -Anxiety subscale sensitivity was 0.88, specificity 0.54 at the optimum cut off of 5/6. A comparison the areas under the curve of the Receiver Operating Characteristics for the two instruments indicated that the area under the curve of the Geriatric Anxiety Inventory was significantly larger than that of the Hospital Anxiety and Depression Scale –Anxiety subscale, supporting its superiority.

Conclusions

The Geriatric Anxiety Inventory is an internally consistent, reliable (stable) and valid instrument with acceptable sensitivity and specificity to screen for anxiety in older inpatients with stroke.

Keywords: stroke, anxiety, screening

Introduction

Stroke is associated with increased incidence of emotional difficulties (1,2). Prominent amongst these is anxiety. Estimates suggest anxiety affects 18% to 25% of people at any stage after stroke (3). Predictors of anxiety after stroke include stroke severity and cognitive impairment (4). Notably it is also associated with less good outcomes, for example reduced quality of life (5,6), social isolation (7) and reduced participation and functional ability (7,8). Thus, it is unsurprising that attention to anxiety after stroke has been recommended in clinical guidance (9).

One issue that arises with respect to the consideration of anxiety after stroke, is how to identify it when it has many similar symptoms to stroke (e.g., physical tension, fatigue, problems concentrating), and where the majority of healthcare staff in regular contact with patients have only limited training in mental health. This requires the provision of screening instruments that are reliable and valid in people with stroke.

A recent review (10) only identified one instrument that met acceptable psychometric criteria for screening for anxiety after stroke, the HADS-A (11). Since that review, an observational instrument has been developed and validated in stroke patients, the Behavioural Outcomes of Anxiety Scale (12,13), but the HADS-A remains the only recommended self-report tool that allows health care professionals to directly screen for anxiety after stroke. However, the HADS-A has been found to be difficult to use by many after stroke on account of its relative complexity (14); it requires those attempting to complete it to consider four different responses with respect to each of seven statements which patients choose to indicate how they have been feeling over the past week. It also has limitations with respect to its use with older people, who make up the majority of those with stroke. It is considered to lack a clear clinical cut off and to be more a measure of general distress than of anxiety (15,16).

The aim of the study was to evaluate the validity and reliability of the GAI (17) a simple binary response instrument designed for use with older people, for screening for anxiety in of older inpatients with stroke. It was expected that the GAI would demonstrate construct validity, when compared to a gold standard clinical interview and with respect to the only other validated self-report instrument, the HADS-A. It was also expected the GAI would be internally consistent and stable over time (reliable) and ROCs could be used to identify optimum cut-offs with acceptable sensitivity and specificity. On the basis of its easier format it was thought participants would prefer the GAI over the HADS.

Methods

Ethical approval was obtained from the South East Coast - Kent NHS National Research Ethics Service (REC12/LO/0256).

Participants were recruited from four units providing inpatient rehabilitation for patients with stroke. Three of the stroke services were in the southeast of England, one was located in the Midlands. Participants were eligible for the study if they were inpatients, had suffered a stroke between 2 weeks and 6 months previously, were 65 years or older, medically stable and gave informed consent. Exclusion criteria included having significant cognitive impairment as represented by a score < 8 on the Abbreviated Mental Test (18) or < 24 on the Mini Mental State Examination (19), or being regarded as having a significant cognitive impairment in the clinical opinion of the lead clinician. In addition patients were not approached if they were considered to have aphasia sufficient to prevent them from participating in an assessment, as ascertained by the lead clinician or speech and language therapist, or if they were considered to suffer from a co-morbid psychiatric disorder other than anxiety or depression, e.g. schizophrenia, dementia or a present psychotic episode, as identified in the medical notes.

Measures used in the study included a Demographic Information Sheet, the Geriatric Anxiety Inventory, the Hospital Anxiety and Depression Scale, the Structured Clinical Interview for DSM-IV Axis 1 Disorders: Research Version.

The Demographic Information Sheet collected background information on participants including age, gender, marital status, living circumstances, previous occupation, level of education, ethnicity, type and date of stroke, major diagnoses, current medication and major life events in the year prior to their stroke.

The Geriatric Anxiety Inventory (17) is a 20-item self-report or administered scale that measures anxiety (over the last 7 days) in older people. Respondents either ‘agree’ or ‘disagree’ to statements (e.g., ‘I worry a lot of the time’; ‘I get an upset stomach due to my worrying’). Research indicates that the GAI has good reliability and validity in both a ‘normal’ sample of older people and in older people attending a psychogeriatric service (17). Scores range from 0 to 20. A cut-off point of 10/11 has been recommended within a psychogeriatric sample for detection of those with DSM-IV Generalised Anxiety Disorder. Sensitivity is .75 and specificity is .84 at this cut off in older adults (17). A recent review of

measures confirmed the GAI as appropriate for use with older people (16). The GAI has demonstrated sound psychometric properties in people with Parkinson's disease (20).

Hospital Anxiety and Depression Scale (HADS) [11]. The HADS was designed for to identify symptoms of anxiety and depression in hospitalised, medically ill patients. It is a 14 item self-reported or clinician administered rating scale with two subscales, one measuring anxiety (HADS-A, 7 items) and the other depression (HADS-D, 7 items). Each item has four responses from which patients choose to indicate how they have been feeling over the past week. Item scores range from 0 to 3, with total scores for each subscale ranging from 0 to 21. Reliability and validity data are available for its use as a screening measure in stroke. O'Rourke et al. (21) found the HADS-A to have a sensitivity of .83 and specificity of .68 at a cut off of 6/7 for anxiety in a study of 111 stroke patients with reference to the Schedule for Affective Disorders and Schizophrenia – (SADS) (22).

The Structured Clinical Interview for DSM-IV Axis 1 Disorders: Research Version (SCID-I-RV) [23] is a semi-structured interview for making the major DSM-IV Axis I diagnoses. Structured clinical interviews are widely accepted as the gold standard for diagnosis of anxiety (24). After administering the overview section, specific sections of the SCID-I-RV were used to confirm a DSM-IV diagnosis of anxiety.

Participants were identified by a designated lead clinician of the service. Eligible patients were approached by the lead clinician or senior staff member to see whether they were willing to receive study information. Those who were willing to be involved were visited at least 24 hours later by a researcher to discuss the study further and to take consent.

The study consisted of three 3 phases. In phase 1 (duration approximately 30 minutes) participants completed the GAI and the HADS with a trained researcher. The order of administration of these measures was counterbalanced to ensure that order effects were minimised. After administration participants were asked which screening measure they preferred to complete. Phase 2 of the study took about 45 minutes and consisted of the diagnostic interview; the overview and anxiety sections of the SCID-I-RV. The SCID-I-RV was administered by a different researcher from the one who conducted phase 1 and also blinded to the results of the screening measures. Phase 2 interviews took place between 24 hours and one week after phase 1, with every attempt made for them to be completed as early as possible within this time frame. Demographic information not available in the medical notes was requested from the participant as part of this interview. In phase 3 (duration

approximately 15 minutes) the GAI was repeated in order to assess test-retest reliability. This phase was scheduled to take place as soon as practicable after phase 2.

Using the point estimate approach of Shoukri, Asyali and Donner25 and general views on testretest reliability which suggest that figures around 0.7-0.8 are 'good'26 and assuming an alpha in the region of at least 0.8 with an 95%CI surety that the alpha lies between 0.7 and 0.9 (i.e. that it is at least 'good') it was determined a sample of at least 52 participants was required. Descriptive statistics were used to describe the study sample. The prevalence of anxiety was assessed by calculating the percentage of participants diagnosed as anxious by the Structured Clinical Interview. Cronbach's alpha was used to establish internal consistency of the Geriatric Anxiety Inventory and Hospital Anxiety and Depression Scale. The scales were then assessed for skewness and kurtosis. Subsequently associations between the scales were assessed using Tau B, including phase1 Geriatric Anxiety Inventory scores with respect to phase 3 Geriatric Anxiety Inventory scores, to establish test re-test reliability.
Receiver Operator Characteristic curves were calculated for the Geriatric Anxiety Inventory and Hospital Anxiety and Depression Scale – Anxiety subscale against the Structured Clinical Interview diagnosis. A Receiver Operator Characteristic curve plots sensitivity against false positive rate (1-specificity). The area under the curve provides a measure of overall performance of a screening instrument and represents the probability that a result for a randomly chosen positive case will exceed the result for a randomly chosen negative case. In this area a score of at least 0.80 is recommended for the sensitivity of a screening measure and test specificity is recommended to be at least 0.60 25. The Receiver Operator Characteristic curves were also used in order to explore the appropriate cut off points to identify a participant as anxious on the Geriatric Anxiety Inventory and on the Hospital Anxiety and Depression Scale – Anxiety subscale in relation to Structured Clinical Interview diagnosis. An Receiver Operator Characteristic curve evaluation was then undertaken to identify whether the Area Under the Curve achieved for the Geriatric Anxiety Inventory was significantly larger than that achieved by the Hospital Anxiety and Depression Scale – Anxiety subscale. Participant preference for a given screening instrument was considered by calculating the percentage of participants with respect to the following categories; 'preference for Geriatric Anxiety Inventory', 'preference for Hospital Anxiety and Depression Scale – Anxiety subscale' and 'no preference'. A one-sample Chi-square test considering only those expressing a preference was conducted.

Results

A total of 91 inpatients were recruited for the study between March 2013 and February 2015. Participant characteristics are summarized in Table 1. Median age was 79 (IQR = 14.5 yrs). Phase 1 data collection occurred at a median of 43 days after stroke (IQR = 39.5 days). The time between phase 1 and phase 2 was a median of 3 days (IQR = 5), time between phase 2 and phase 3, a median of 3 days (IQR = 5), and time between phase 1 and phase 3, 7 days (IQR = 5.5). Sixty nine of 81 participants completed phase 2 (85%) and 53/81 (65%) phase 3. All loss to follow-up was on account of discharge from hospital. There was no statistical evidence those lost to follow-up differed from those retained on anxiety level or demographic variables.

Insert table 1 about here

Table 2 displays the distribution of scores on the GAI, the HADS-A, HADS-D and SCID-I-RV. The DSM-IV criteria for Generalised Anxiety Disorder at phase 2 were met by 8/69 (11.6%) participants. There were modest but significant correlations between years of formal education and anxiety; more education was associated with less anxiety (GAI τB = -.31, n = 81, p < .01; HADS-A τB = -.32, p > .01. No other demographic characteristics were significantly associated with anxiety. GAI scores at phase 1 were positively skewed (skew = 1.31, SE = .27, n = 81) with most participants reporting low levels of anxiety. This was also the case at phase 3 (skew = 1.76, SE = .30, n = 63).

Insert table 2 about here

The internal consistency of the GAI (phase 1 α = .95, phase 3 α = .95), the HADS-A (α = .83) and the HADS-D (α = .64) was acceptable. The GAI demonstrated acceptable test–retest reliability (τ_B = .53, n = 63, p < .001). As evident in Table 3, item if deleted statistics supported the inclusion of all the GAI questions.

Insert Table 3 about here

Total scores on the GAI significantly correlated with the HADS-A, (τ_B = .61, n = 81, p < .001) supporting construct validity. Good discriminant validity was demonstrated by this figure being much higher than the association with the HADS-D (τ_B = .28, n = 81, p = .001). This suggests that the GAI is a more valid measure of anxiety than depression.

Figure 1 displays the ROC curve for the GAI and the HADS-A with respect to the SCID diagnosis. The optimum cut off on the GAI to detect anxiety was 6/7. At this level acceptable sensitivity (.88) and specificity (.84) were demonstrated providing evidence of convergent validity. The optimum cut off for the HADS-A was 5/6 which achieved an identical sensitivity of .88 but a lower specificity of .46. The GAI misclassified 10/61 participants as having anxiety when this was not the case based on the SCID, the HADS-A however misclassified 28/61 participants. Areas under the ROC curves (AUCs) were compared between the GAI and HADS-A following the non-parametric testing procedures outlined by DeLong et al. (26) and implemented in R in the pROC package (27). This indicated that the AUC of the GAI of .84 (95%CI .65 – 1.00) was significantly larger than that of the HADS-A (.75, 95%CI .53 - .96; Z = 1.76, p = 0.04, one-tailed).

Inset Figure 1 about here

A total of 39 (48%) of participants preferred to complete the GAI, 26 (32%) preferred the HADS-A and 16 (20%) expressed no preference. The difference between preferences for the GAI over the HADS-A was not significant, $X2$ = 2.60, df = 1, p = .107, however it is noted 68% preferred the GAI or had no preference.

Discussion

The GAI was found to have acceptable internal consistency and test re-test reliability in a sample of older people with stroke in an inpatient setting. Discriminant validity with respect to depression was acceptable. The optimal cut-off for the GAI with respect to SCID diagnosis was 6/7. This is lower than in an older adult psychiatric sample (17), but is consistent with other studies of anxiety after stroke (22,28-30). At this cut-off acceptable sensitivity and specificity was evident, and superior to the comparison instrument the HADS-A. The HADS-

A has demonstrated higher specificity in other studies of people with stroke (22,28-30) however in none of these were participants restricted to older people. The current findings support the concerns expressed about the utility of the HADS-A when used with people aged 65 years and over (15,16).

This study used a structured clinical interview as the gold standard for anxiety. This was administered blind to, and regardless of, scores on the screening instruments. However there are a number of limitations to the study that need to be acknowledged Firstly, the rate of anxiety identified was low (11.6 %) as compared to prevalence studies which suggest a rate of 18% via interview (3). However, this low rate is not surprising given a hallmark of anxiety is avoidance (31); patients with anxiety may have been less likely to agree to participate in research focusing on this issue. This focus was rarely the case in studies on which prevalence estimates are based (3). In addition anxiety is associated with cognitive impairment in people with stroke (4). Therefore some people with anxiety may have been excluded on this basis. Cognitive impairment exclusion criteria may not have been applied or may have been less rigorously applied in prevalence studies. Of further concern is that because of discharge from the hospital some 15% of study participants were lost from phase 1 to phase 2. These issues raise questions about the representativeness of the sample obtained and therefore the weight that might be placed on the current findings. Further the participants in this study were all inpatients, having relatively recently had a stroke. The results of this investigation may not apply to those in the community after stroke. Sensitivity and specificity have been found to vary at different time periods relative to certain cut offs after stroke (32). This is an important consideration as the high rate for anxiety after stroke is relatively stable over time (3).

Further research is required to develop and improve scales like the GAI to better identify anxiety after stroke, particularly to reduce the false positive rate. In addition studies are needed of screening measures for those living in the community after stroke. Responsiveness to change in anxiety was not considered in the current evaluation. This is important to consider as treatments become available that can address this problem in older people after stroke (33-35).

Contributions

Conception and design of the study (IK, CF-S, HH) acquisition of data (NL) analyses (CF-S) interpretation of data (IK, CF-S, HH) drafting the article (IK, CF-S, HH) revising the article critically for important intellectual content and final approval of the version to be submitted(IK, CF-S, NL, HH).

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Declaration of interest None

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Table 1 *Participants' characteristics at phase 1*

Characteristics	**n**	**%**
Age in years		
65-74	25	30.9
75-84	29	35.8
85-94	26	32.1
≥ 95	1	1.2
Gender		
Men	42	51.9
Women	39	48.1
Married/partnered		
Yes	41	52.6
No	37	47.4
Missing	3	3.7
Place of residence at time of stroke		
Living at home	70	86.4
Warden assisted	5	6.2
Other	6	7.4
Type of stroke		
Ischemic	68	87.2
Haemorrhagic	10	12.8
Missing	3	3.7
Side of lesion		
Right	43	53.1
Left	31	38.3
Bilateral	3	3.7
Other (spinal)	1	1.2
Previous stroke		
Yes	20	25.6
No	58	74.4
Missing	3	3.7

Measure	n	Mean	SD	Range
GAI Phase 1	81	4.41	5.80	0 – 20
HADS-A Phase 1	81	5.47	4.57	0 – 18
HADS-D Phase 1	81	5.33	3.56	0 – 16
HADS Total Phase 1	81	10.80	7.29	0 – 33
GAI Phase 3	53	3.68	5.37	0 – 20

Table 2 Summary of results of mood screening

Note: GAI = Geriatric Anxiety Inventory, HADS-A = Hospital Anxiety and Depression Scale - Anxiety subscale, HADS-D = Hospital Anxiety and Depression Scale - Depression subscale, HADS Total = Hospital Anxiety and Depression Scale - Total Score (HADS-A + HADS-D).

Item number	GAI phase 1		GAI phase 3	
	Proportion endorsing item (N=81)	Corrected-item correlation	Proportion endorsing item (n= 63)	Corrected item total correlation
1	29.6	.60	23.8	.65
2	27.2	.53	15.9	.53
3	21.0	.57	9.5	.65
4	34.6	.62	36.5	.50
5	21.0	.79	15.9	.75
6	28.4	.68	20.6	.74
7	18.5	.66	11.1	.58
8	25.9	.65	30.2	.66
9	21.0	.77	23.8	.73
10	24.7	.84	22.2	.76
11	32.1	.74	27.0	.69
12	11.1	.57	7.9	.55
13	12.3	.62	15.9	.75
14	19.8	.52	20.6	.58
15	21.0	.60	15.9	.53
16	22.2	.80	15.9	.83
17	16.0	.79	17.5	.72
18	14.8	.49	6.3	.57
19	16.0	.81	12.7	.79
20	22.2	.75	19.0	.83

Table 3

Geriatric Anxiety Inventory (GAI) item statistics.

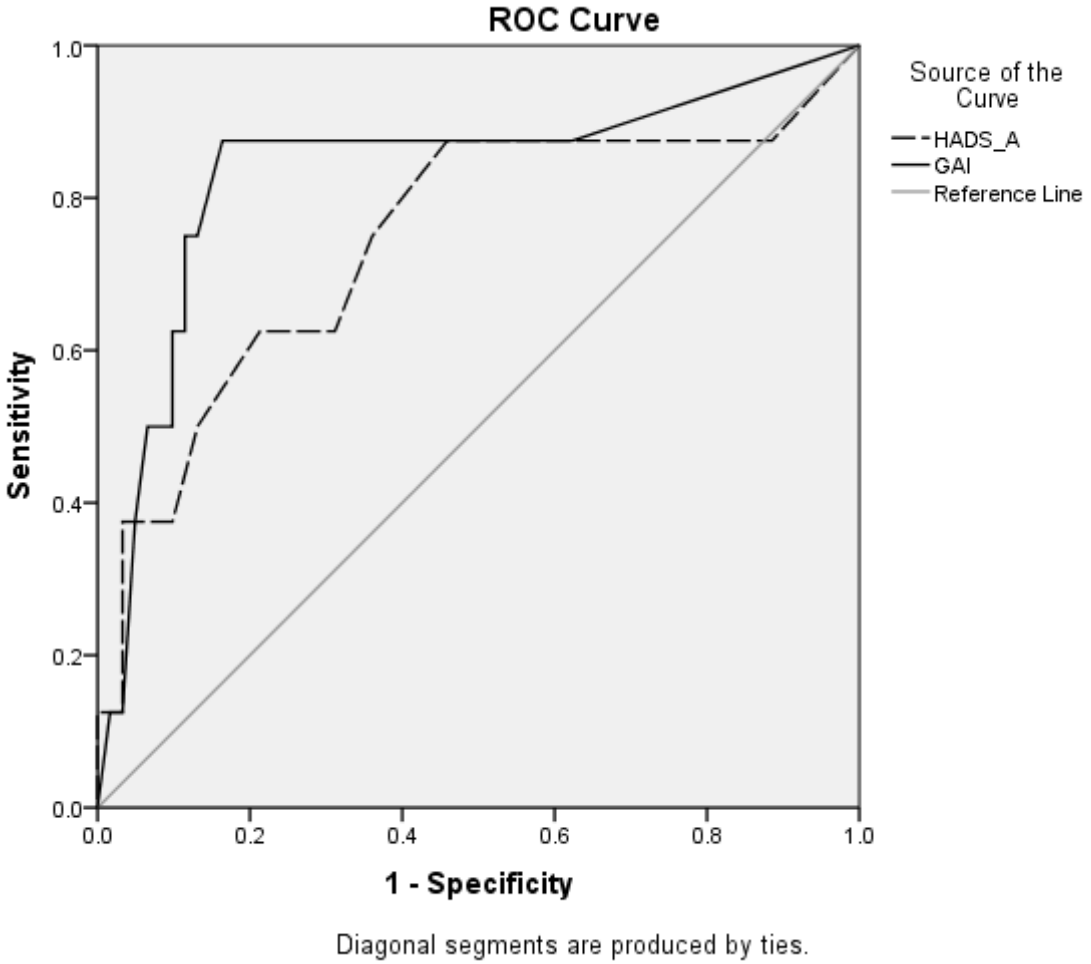

Figure 1. Receiver Operating Characteristic (ROC) curves for the Geriatric Anxiety Scale (GAI) and the Hospital Anxiety and Depression Scale - Anxiety sub scale (HADS-A) with respect to anxiety diagnosis on the Structured Clinical Interview for the Diagnostic and Statistical Manual for Mental Disorders 4th Edn. (SCID).