Chapter 3
Diagnostic Tools for Anxiety and Depression

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Introduction

Depression and anxiety are common in patients with COPD. The prevalence of depression in patients with COPD ranges between 8 to 80% and 6 to 74% for anxiety symptoms [1, 2]. This is similar to patients with chronic heart failure (CHF) estimated between 10 and 60% for depression and 11–45% for anxiety [1]. The exact mechanism and factors that contribute to the elevated level of anxiety and depression in patients with COPD are unknown. They are most likely to be multi-factorial. Moderate-to-severe COPD patients are most likely to experience severe limitation in their daily activities due to loss of energy and severe breathlessness, higher frequency of hospitalisations due to acute exacerbations, and being housebound due to the progressive disabling nature of the condition [1, 2]. Indeed, these factors may contribute to additional burden and may dislocate coping mechanisms when they are compounded with mood disorders in patients with COPD.

The diagnoses of both major depressive and anxiety symptoms are complicated in patients with COPD due to overlap of symptoms due to physical ill health. In addition, some of the difficulties may include lack of knowledge or understanding of depression by patient and carers; a fear of rejection by the society; the tendency to avoid psychiatric care because of stigma; and the reduction of social and work contacts which makes depression a relatively hidden disorder [3–5]. Indeed, psychiatric assessment in old age may be more complicated, for example, the physician may be unable to extract detailed history because of cognitive impairment, denial or reluctance by the patient.

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There is increased recognition that anxiety and depression have considerable impact on patients' health status and healthcare utilisation. However, there are no disease-specific tools that have been developed and validated to asses these symptoms in patients with COPD. Currently, a number of screening tools have been used in research and in clinical practice to assess anxiety and depressive symptoms. Therefore, it is important for clinicians and researchers to have an in-depth understanding of their strengths and limitations of these tools. This chapter reviews the most commonly used screening tools for anxiety and depressive symptoms in patients with COPD, primarily developed and employed to assess these symptoms for patients with or without chronic conditions. Furthermore, the review provides clinicians with practical tips when to use (clinical diagnostic tools) or refer patients to psychologist/psychiatrist for further assessment. It will also provide some guidance areas for future research and outcome measures that have been used in clinical trials.

What Are the Potential Difficulties Associated with Detection?

If mood and anxiety disorders are so common, why are they often undiagnosed and untreated in COPD? First, screening tools for depression or anxiety symptoms are not routinely used in clinical practice. Second, depressive and anxiety symptoms in patients with COPD might be masked by physical symptoms such as decrease in exercise tolerance, breathlessness, fatigue and increased dependency in daily activities. Furthermore, in patients with COPD, poor health, bouts of chest infection and frequent episodes of hospital admission are so common as to be almost accepted scenario for many patients. In this context, patients may not disclose depressive or anxiety symptoms unless they are specifically asked [6]. Other contributing factors might be that not all physicians are confident enough to pursue psychiatric assessment and patients may fear approaching their physicians because of the stigma of mental illness. Lack of public awareness fuels this continued stigma [5] and depression itself is associated with its own specific stigma [7] and fear of anxiety during social interaction.

Screening Tools for Anxiety and Depression

The purpose of a screening tool is to identify those patients who are in need of further psychiatric examination. Identifying high numbers of false positives is costly, both financially, and in terms of wasted time for the clinician and the patient. A scale that can efficiently screen patients for anxiety and depression is

characterised by a high sensitivity, which ensures that all individuals with an anxiety disorder are identified [8].

Self-report rating scales are designed to be measurement instruments that quantify patients' subjective experiences and aid the clinician in identifying, quantifying and tracking changes in these important but not directly observable variables [9]. Self-report scales typically fall into two groups: screening scales and symptom-rating scales. Screening scales are designed to identify the presence or absence of a specific disorder, such as a personality disorder, and provide a dichotomous outcome (i.e. case or non-case). In comparison, symptom-rating scales are designed to quantify the severity of symptoms. This may involve measuring the severity of symptoms in a prediagnosed disorder, or monitoring of subclinical symptoms [9]. Although rating scales quantify symptom severity, many also report cut-off scores that can be used to indicate possible clinical disorders in a dichotomous fashion.

Self-report scales have become increasingly popular since the 1940s due to a growing need for reliable and valid outcome measures for both research and clinical practice. In addition, Kessler et al. suggest [10] that there are a number of important practical benefits to self-report scales. First, they are relatively inexpensive to develop and distribute. Second, the continuous measurement approach is better suited to the understanding of diverse symptoms than a dichotomous clinician judgement. Third, the psychometric properties of self-report scales are easier to record than clinician judgement.

Self-report scales fulfil, if developed appropriately, many of the criteria that are required from an outcome measure. For example, a survey of Canadian clinicians found high levels of agreement that outcome measures used in clinical practice should have the following characteristics: brevity, simplicity, ease of scoring, reliability, validity and sensitivity to change [11].

Although self-report scales have a number of strengths that make them suitable for both clinical and research settings, there are a number of factors which influence their effectiveness and application. These fall under two main categories: response distortions and psychometric properties. Response distortions refer to response styles (such as acquiescence bias, extreme and central tendency responding) and response sets (such as social desirable responding), whereas psychometric properties refer principally to reliability and validity.

Assessment and Diagnostic Tools

The use of psychological screening tools for assessment anxiety and depression in older people with co-morbid physical illness [12] may allow healthcare professionals:

- to increase early detection of depression and anxiety;
- to plan treatment action in those identified with symptoms;

- to monitor changes over time in the patient's condition;
- to evaluate the response of the older person after intervention;
- to tailor individual's patient needs in clinical and rehabilitation programme;
- to provide appropriate support to family and care givers;
- to reduce the risk overlooking important patients symptoms.

In this regard, early detection of depression and anxiety play an important role in the management of patients with COPD. The commonly employed screening tools for depression and anxiety in patients with COPD are listed in Tables 3.1 and 3.2. When an individual patient responds positive (suffering with depression and anxiety using a screening tool), he/she should be assessed further for the cause(s) of current depressive or anxiety episode by the healthcare professionals (e.g. general physician). Therefore, thorough physical examination will help to focus on the patient's problems and to devise appropriate (individually tailored evidence-based treatment) including referring patients for further assessment.

Table 3.1 Depression screening scales

Scale	Number of items	Mode of administration	Duration (min)	Application	Timeframe (days)	Response options	Score range
BDI	21	Self or interviewer	5	Screening tool	21	Likert 0–3	0–63
HADS (depression)	7	Self	2–5	Screening tool	7	Likert 0–3	0–21
BASDEC	19	Interviewer using deck of cards	4	Screening tool	14	Yes or No. (1, 0) or I do not know (0.5)	0–21
CES-D	20	Self or interviewer	5–10	Screening	7	Likert 0–3	0–60

BDI Beck Depression Inventory; *HAD* (depression); *BASDEC* Brief Assessment Depression Examination Cards; *CES-D* Centre for Epidemiologic Studies Depression Scale

Table 3.2 Anxiety screening scales

Scale	Number of items	Mode of administration	Duration (min)	Application	Timeframe	Response options	Score range
BAI	21	Self or interviewer	5	Screening tool	21 days	Likert (0–3)	0–63
HADS (anxiety)	7	Self	2–5	Screening tool	7 days	Likert (0–3)	0–21
STAI (trait anxiety)	20	Self	10	Screening tool	"Right now"	Likert (1–4)	20–80
GAI	20	Self or interviewer	5–10	Screening	7 days	Disagree or agree (0–1)	0–20
AIR	10	Self	3	Screening	14 days	Likert (0–3)	0–30

BAI Beck Anxiety Inventory; *GAI* Geriatric Anxiety Inventory; *HADS* Hospital Anxiety and Depression Scale; *STAI* State-Trait Anxiety Inventory; *AIR* Anxiety Inventory Respiratory Disease

Depression

Diagnostic Criteria for Major Depression

Depressive episode is a syndrome that includes depressed mood, anhedonia (loss of interest or pleasure) and fatigue that is present for a period of at least 2 weeks.

Diagnosis is made by a structured interview using the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) (American Psychiatric Association [13]) criteria. Major depressive episode may include: five (or more) of the following symptoms have been present during the same 2-week period and represent a change from previous functioning; at least one of the symptoms is either (1) depressed mood or (2) loss of interest or pleasure.

1. Depressed mood most of the day, nearly every day.
2. Markedly diminished interest or pleasure in all or most activities.
3. Weight changes more than 5% of body weight in one month, including weight loss without dieting, and a decrease or increase in appetite.
4. Insomnia or hypersomnia nearly every day.
5. Psychomotor retardation or agitation.
6. Loss of energy, or fatigue.
7. Feelings of worthlessness or guilt.
8. Inability to concentrate or make decisions.
9. Recurrent thoughts of death, or suicidal ideas or suicide attempt.

It takes about 30 min to administer the scale and the gold standard for the diagnosis of bout major and minor depressive symptoms. However, the downside of the scale is time-consuming and requires special training to administer the scale.

Geriatric Mental State Schedule (GMS)

The Geriatric Mental State Schedule [14] is a well validated scale used to diagnose clinical depression and anxiety in elderly people including those with chronic diseases. It is one of the most widely used and respected instruments for measuring a wide range of psychopathology in elderly people. It is based on the Present State Examination [15] and the Psychiatric State Schedule [16]. It has been adopted for use on laptop computer via software which generates a diagnosis, the Automated Geriatric Examination for Computer Assisted Taxonomy (AGECAT) [17], and is replicable (when used in hospital and community samples) against psychiatrists' diagnosis [17]. Its internal validity and reliability have been established [18], and it has been used in a cross-national setting [19]. The GMS delivers a diagnosis using a hierarchy which corresponds to approaches to diagnosis by a trained psychiatrist. There are 5 levels of severity generated by GMS for 5 diagnostic groups and a level of 3 or above corresponds to a "case". Thus, level 3 and above in the depression

group is diagnostic of clinical depression, and level 3 or above in the anxiety group diagnostic of clinical anxiety. It requires a trained member of staff for the interview and takes about 40 min to administer.

Montgomery–Asberg Depression Rating Scale (MADRS)

The MADRS assesses severity of clinical depression [20], has been validated in medically ill elderly patients and is widely used in the context of other chronic diseases. It has ten items scored compositely which result in a maximum total score of 60. It classifies severity of depression into four categories: normal, i.e. not depressed (0–6); mild (7–18); moderate (19–34); and severe (>35) [21]. Low scores imply mild depression and high scores correspond to severe depression. Subjects rate their responses using a Likert 7-point category scale, for example, 0 = "no sadness", 6 = "miserable all the time". The MADRS has performed better in identifying responders and non-responders to antidepressant drug therapy than the Hamilton Depression Rating Scale (HDRS) [20]. A study by Hammond [22] identified the inappropriateness of HDRS (because of very low internal consistency) in determining severity of depression in the physically ill-depressed elderly patients but recommended the MADRS as a preferable choice. A study by Yohannes et al. [23] using the MADRS scale in patients with COPD identified the severity of depression 17 (30%) were mildly depressed (MADRS score 7–19), 39 (68%) were moderately depressed (MADRS score 20–34) and 1 (2%) was severely depressed (MADRS score 35–60). It requires a trained person to administer the scale.

The Hamilton Depression Rating Scale (HDRS)

The HDRS measures the severity of depression and change in depressive symptoms [24]. It is a clinician-rated scale and takes about 20–30 min to complete. The 17 items of HRDS, a score of 0–7 is generally accepted within the normal range, (or in clinical remission), whilst a score of 20 or higher (indicating at least moderate severity) is usually is required medical intervention (entry into a clinical trial). Subjects rate their responses using a Likert 4-point category scale, for example, 0 = "absent", 4 = "attempts at suicide". This is a widely used clinical assessment tool to assess the responsiveness to intervention, e.g. antidepressant drug therapy.

Brief Assessment Schedule Depression Cards (BASDEC)

BASDEC is a valid screening tool for depressive symptomatology in elderly medically ill patients [25]. It consists of a 19-item deck of cards, self-administered

as "true", "false" and "I do not know" responses. Two items are weighted to 2 points; other affirmative responses, 1 point; and "I do not know" 0.5 point with a maximum score of 21. A score of seven or above suggests a "case" of depression [25]. The BASDEC demonstrated a good response when tested against the "gold standard" of the Geriatric Depression Score (GDS) which is recommended as an assessment scale for elderly people by the British Geriatrics Society/Royal College of Physicians [26]. The BASDEC performed well as a screening tool in elderly medically ill inpatients compared with the GDS having a sensitivity of 71%, a specificity of 88%, a positive predictive value of 74% and a negative predictive value of 86% [25]. Studies suggest that BASDEC is user-friendly and can be administered by a non-medical personnel. It takes about 4 min to complete. The BASDEC scale has been validated in patients with COPD. The BASDEC scale performed well against the GMS: having a sensitivity of 100%, a specificity of 93%; a positive predictive value of 91% and a negative predictive value of 100% [23]. The kappa score of BASDEC $\geq$7 against GMS $\geq$3 was 0.93. However, the BASDEC has not been adequately tested to test the efficacy of clinical intervention in patients with COPD. The minimal clinical importance difference is unknown.

Centre Epidemiologic Scale for Depression (CES-D)

The centre epidemiologic scale for depression (CES-D) is a self-complete questionnaire comprising of 20 items. Each item has a 4-point response choice ranges from 0 to 3. A total score of $\geq$16, out of 60 points, is considered to indicate the presence of depression [27]. In addition, the CES-D score can be employed as a continuous measure where higher scores are indicative of elevated depressive symptoms. It measures the presence of depression into three categories: normal, i.e. not depressed (0–15); mild (16–21); and moderate-to-severe depression (>21) [27]. In a recent study, it was found that CES-D has a sensitivity of 80% to identify major depression and a specificity around 70% [28] in COPD patients. However, further work is required to examine the efficacy of CES-D to detect clinically relevant change following an intervention in patients with COPD.

Beck Depression Inventory (BDI)

Beck's depression inventory (BDI) is a 21-item self-administered rating inventory measuring attitudes and symptoms of depression, with high internal consistency, and good discriminates and convergent validity [29, 30]. It is scored 0–3, with the scores range from 0 to 63. The optimal cut-off score in the BDI $\geq$19 distinguishes patients with minimal or mild depressive symptoms from patients with moderate or severe depressive symptoms [30]. This cut-off point was previously used in a recent prospective study that enrolled COPD patients in a randomised controlled clinical

trial [30]. It has been recommended as a clinical screening tool for depression in COPD patients by the American College of Chest Physician [31].

Anxiety

Anxiety may be defined as an apprehensive anticipation of danger or stressful situations associated with excessive feelings of dysphoria or somatic symptoms of tension. Symptoms of anxiety include feelings of restlessness, difficulty concentrating, muscle tension, fatigue, irritability and sleep disturbance. Panic is characterised by a sudden onset of physical symptoms including breathlessness, chest pains and trembling sensations, alongside psychological symptoms that include intense fear, fear of dying and detachment [13].

Two of the most prevalent and recognisable anxiety disorders in patients with COPD are generalised anxiety disorder (GAD) and panic disorder (PD) with or without agoraphobia, which affect up to 33 and 41% of patients, respectively [32]. In contrast, the prevalence of GAD among community-based older adults is between 1 and 7%, whilst the prevalence of PD (with or without agoraphobia) is between 0.1 and 2% [33, 34]. Estimates of anxiety prevalence based on threshold scores on self-report anxiety scales suggest that clinically significant symptoms of anxiety may be present in up to 74% of patients with COPD [23].

Despite the high prevalence of anxiety disorders in patients with COPD, there has been surprisingly little focus upon anxiety within the literature. This is also the case among the general elderly population, where anxiety remains less well studied than other psychiatric disorders such as depression [35]. Findings from a recent study by Kunik et al. [36] indicate that anxiety is less recognised than depression in patients with COPD. Kunik et al. [36] found that 43% of patients with a depressive disorder had been previously diagnosed, compared to only 29% of patients with an anxiety disorder.

There is growing evidence to suggest that co-morbid anxiety in patients with COPD impacts negatively on a number of key measurable outcomes including functional status, health-related quality of life (HRQoL) and healthcare utilisation [37–39]. Anxiety may also be a major predictive factor for increased hospital admissions for acute exacerbation of COPD (AECOPD) in the elderly [23]. Anxiety also has a significant emotional impact in patients with COPD. Qualitative accounts from patients with COPD indicate that co-morbid anxiety is associated with intense fear, inextricable breathlessness and near-death experiences [40–42]. However, remarkably little is known about how patients with COPD experience anxiety, particularly which symptoms are most common and how these interact with respiratory disease.

The “gold standard” diagnosis of anxiety is through psychiatric interview with a qualified practitioner, yet this is often impractical due to the time-consuming nature of the interview. Therefore, routine screening for anxiety is typically undertaken using specifically designed scales, which can identify patients who may have

clinically significant symptoms of anxiety requiring further investigation. Current clinical guidelines for COPD, such as those from the American College of Chest Physicians [31] and Global Initiative for chronic Obstructive Lung Disease [43], advocate routine screening for anxiety. Yet, although there are a number of anxiety screening scales in existence, co-morbid anxiety remains poorly recognised and undermanaged [31, 43, 44]. For example, Kunik et al. [36] found that among 204 patients with COPD and clinically significant anxiety or depression, only 31% were receiving treatment. Furthermore, only 46% of patients with severe anxiety or depression were receiving treatment [36]. In another chart review of 102 patients with COPD, only 47% of patients with a clinical anxiety disorder were identified and followed by primary care providers or mental health providers [44].

Diagnostic Criteria for Anxiety Syndromes

The DSM-IV criteria [12] define generalised anxiety Disorder as follows:

- Excessive anxiety and worry (apprehensive expectation), occurring more days than not and for at least 6 months, about a number of events or activities (such as work or school performance).
- The person finds it difficult to control the worry.
- The anxiety and worry are associated with three (or more) of the following six symptoms (with at least some symptoms present for more days than not for the past 6 months). Note: only one item is required in children.

(1) restlessness or feeling keyed up or on edge.
(2) being easily fatigued.
(3) difficulty concentrating or mind going blank.
(4) irritability.
(5) muscle tension.
(6) sleep disturbance (difficulty falling or staying asleep, or restless unsatisfying sleep).

- The focus of the anxiety and worry is not confined to features of an Axis I disorder. For example, the anxiety or worry is not about having a panic attack (as in panic disorder), being embarrassed in public (as in social phobia), being contaminated (as in obsessive compulsive disorder), being away from home or close relatives (as in separation anxiety disorder), gaining weight (as in anorexia nervosa), having multiple physical complaints (as in somatisation disorder), or having serious illness (as in hypochondriasis), and the anxiety and worry do not occur exclusively during post-traumatic stress disorder.
- The anxiety, worry or physical symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- The disturbance is not due to the direct physiological effects of a substance (e.g. a drug of abuse, a medication) or general medical condition (e.g. hyperthyroidism)

and does not occur exclusively during a mood disorder, a psychotic disorder or a pervasive developmental disorder.

Researchers and clinicians, who recognise the need to identify patients with clinically significant anxiety and/or to measure anxiety levels to monitor interventions, have called for a reliable and easily administered screening and measurement tool [36, 45]. However, as Jain and Lolak asserted [46] in 2009, the most appropriate "gold standard" anxiety screening instrument for patients with COPD was yet to be identified. The majority of anxiety screening instruments that are used in clinical practice and within research settings have been developed in and for young healthy populations. Few scales have been specifically developed for use in elderly populations and none have been developed specially for patients with COPD where there is a lack of standardisation of appropriate measures [47]. Clinical guidelines recommend scales such as the Hospital Anxiety and Depression Scale-Anxiety (HADS-A [48]), Beck Anxiety Inventory (BAI [29]) and Depression Anxiety Stress Scales (DASS [49] for measuring and screening anxiety in patients with COPD. However, these scales, although popular within COPD-related research and clinical practice, have a number of documented shortcomings that may make them unsuitable for use in patients with chronic somatic disease, particularly COPD.

Whilst all people experience anxiety to some degree, most do not develop long-term anxiety disorders. Chronic, persistent or severe anxiety is typically classified, in terms of a medical approach, into one of the specific anxiety disorders (PD or GAD, for example), such as those proposed by the DSM-IV-TR criteria [12] or International Classification of Diseases-10 world health organisation [50]. This categorical system allows clinicians to decide whether or not to treat the patient. However, McDowell [51] posits that psychologists, in contrast to medical doctors, typically take a dimensional approach to anxiety, which treats the associated symptoms of anxiety on a continuum of severity. This distinction is characterised by the two styles of measurement: the medical model of dichotomous case or non-case, categorised by a clinical diagnosis, and the psychological model of ordinal measurement of symptom severity, often measured using scales and questionnaires.

Steps for Anxiety and Depression Management

GOLD [43] and NICE [52] guidelines recommend that all newly diagnosed COPD patients should undergo a detailed medical assessment, including the assessment of anxiety symptoms. The NICE [52] guidelines for COPD also indicate that clinicians should be alert to the presence of anxiety or depression in their patients. However,

these COPD-specific guidelines fail to recommend clear strategies for identifying anxiety in this patient group. Although NICE (2010) guidelines [52] on the management of GAD and PD (with and without agoraphobia) recommend that a formal diagnosis of anxiety should be undertaken using a structured clinical interview, this is not always practical. Therefore, it is recommended that COPD patients seen in clinical settings are screened using self-report screening tools [31]. In clinical settings, a two-step approach is often incorporated in which patients are first screened using brief, inexpensive scales. Those patients who screen positive for anxiety usually undergo a more thorough assessment to confirm diagnosis with a clinical interview [53].

There are a number of barriers to the detection of anxiety and depression in patients with COPD. These typically fall into patient- or clinician-level barriers. Patient-level barriers to anxiety and depression detection include the stigma associated with mental illness which may lead patients with anxiety to exaggerate somatic complaints instead of acknowledging emotional problems, the reluctance to disclose anxiety symptoms and the confusion or masking that may occur in physical symptoms. Clinician-level barriers include the lack of a standardised assessment approach for patients with COPD, the lack of a disease-specific screening tool, the poor utilisation and uptake of existing screening tools, lack of confidence, skills and knowledge of anxiety symptoms and disorders, and the stigma of mental illness [1, 31, 36].

Such barriers may help to explain why in one recent study exploring the prevalence of anxiety disorders in patients with COPD, less than a third (29%) of patients with a clinical anxiety disorder had received a physician's diagnosis [36].

In clinical practice and research settings, monitoring of anxiety symptoms and screening of anxiety disorders is typically undertaken using self-report anxiety scales. The following section focuses specifically on these scales and critically discusses their use in patients with COPD.

Extant Anxiety Scales

There are number of different scales have been utilised for the measurement and screening of anxiety symptoms and disorders in patients with COPD. Within this section, we critically review five scales that have been either recommended by clinical guidelines for COPD, are widely utilised in COPD-related research and/or are validated for use in patients with COPD (see Table 3.2). A summary of the scales' psychometric properties is provided, with a focus on reliability and validity. Also, where appropriate, recommended cut-off values will be discussed in order to assess the clinical utility of these scales to screen for anxiety disorders.

Beck Anxiety Inventory (BAI)

Beck et al. [29] inventory is a self-report measure that was specifically designed to minimise confounding symptoms with depression and avoid the non-specific dimension of negative affect. The scale contains 21 items, with 14 items reflecting somatic symptoms of anxiety and panic. The BAI is recommended by the ACCP as a viable screening tool for use in COPD patients [31]. A few studies have utilised the BAI in COPD-related research [37, 54], yet the scale remains one of the most common instruments for measuring anxiety in general medical research [55].

Items are presented as a list of symptoms with respondents asked to rate on a four-point scale how much they have been bothered by each symptom in the preceding week. Scores range from 0 to 63. Beck and Steer's [56] manual suggests that a cut-off point of ≤ 9 indicates normal levels of anxiety; 10–18 mild-moderate levels of anxiety; 19–29 moderate-severe levels of anxiety, and 30–63 severe levels of anxiety.

The reliability of the BAI appears to be very high. A review by McDowell [51] found 16 studies reporting Cronbach's α for internal consistency of 0.86–0.94 across a range of populations, including elderly medical outpatients, psychiatric patients and healthy populations. Test-retest reliability for the BAI is reported to be 0.73 for one week and 0.67 for 11 days [57].

The factor structure of the BAI has been explored by Hewitt and Norton [58] and Creamer et al. [59] with both studies finding a two-factor solution: one factor of cognitive symptoms and a second factor representing somatic symptoms. McDowell [51] reviewed studies reporting on the convergent validity of the BAI and found correlation coefficients of 0.44–0.68 with the STAI and 0.47–0.67 with the Hamilton Anxiety Rating Scale for Anxiety. Steer et al. [60] explored whether the BAI could distinguish between elderly medical patients (without psychiatric disease) and psychiatric outpatients to establish whether the high number of somatic symptoms in the BAI may lead to false positives. Although the BAI performed generally well in discriminating between groups, the authors note that six of the somatic items did not distinguish between medical patients and psychiatric patients.

Although Beck et al. [29] claim that the BAI can be used both as a screening tool for anxiety disorders and as an outcome measure for anxiety symptoms, others contend that the BAI is not a measure of anxiety in general but rather a measure of symptoms of panic [61]. The BAI appears to have good face validity for symptoms of PAs, querying 10 of the 14 symptoms listed in DSM-IV-TR classification [12]. However, it has limited face validity for detecting GAD, as it does not include worry-type symptoms that are integral to a DSM-IV-TR diagnosis [62]. This assertion is supported by a recent FA, which suggests that the strongest quality of the BAI is to assess panic symptomatology [63]. Leyfer et al. [63] conclude that whilst the BAI has achieved significant discriminant validity for detecting patients

with PD, it has sacrificed construct validity for assessing overall anxiety. This is probably because Beck et al. [29] deliberately excluded items which may overlap with depression, particularly symptoms associated with GAD (e.g. restlessness, irritability or fatigue). Cox et al. [61] argue that the BAI is compromised as a tool for measuring general anxiety and should be considered a measure of panic.

Geriatric Anxiety Inventory (GAI)

The GAI [35] is a recently developed scale which was designed specifically for use in older populations. It was designed to minimise fatigue by being brief, minimise symptom overlap of medical conditions by excluding somatic items, and utilises a dichotomous scoring format for ease of use in patients with mild cognitive impairment. The GAI is a 20-item scale consisting of statements with an agree/disagree response format. Respondents are asked to reflect on the previous week when answering the items.

Although the GAI has only recently been developed, there are some early data relating to the scale's reliability and validity. Pachana et al. (2007) report [35] a Cronbach's α for internal consistency to be 0.91 and 1-week test-retest reliability of 0.91 in a geriatric psychiatric sample. Other studies exploring the psychometric properties of the GAI in patients with Parkinson's disease have found a Kuder–Richardson coefficient of 0.95 [64], whilst Cheung et al. (2012) report [65] a Cronbach's α of 0.92 in patients with COPD.

Pachana et al. [35] demonstrated that the GAI correlated significantly with a number of extant scales including the BAI and STAI. The optimal cut-off score for identifying patients with an anxiety disorder was found to be 8/9, which correctly classified 78% of patients with a sensitivity of 73% and a specificity of 80%. However, a study exploring the sensitivity and specificity of the GAI in detecting anxiety disorders in older patients with COPD has recently been undertaken that found a significantly lower cut-off score of 2/3. This correctly identified 80% of the sample with a sensitivity of 86% and a specificity of 78% [65].

Although Pachana et al. [35] claim the original GAI is unidimensional in nature, they present no empirical data to support this assertion. In response, a study exploring the psychometric properties of the Spanish version of the GAI found three factors: cognitive symptoms, arousal-related symptoms, and, perhaps surprisingly considering the conceptual model of the scale, a factor containing somatic symptoms [66]. Four of the items of the GAI loaded predominantly onto the somatic factor indicating that the GAI may indeed have a confounding somatic element. Item 7 "I often feel like I have butterflies in my stomach", item 12 "I get an upset stomach due to my worrying" and item 18 "I sometimes feel a great knot in my stomach" all had factor loadings of >0.7 which suggests that these stomach-related items do not fit the non-somatic model of anxiety originally proposed by Pachana et al. [35].

Hospital Anxiety and Depression Scale (HADS)

The HADS [48] was designed as a self-assessment scale for detecting clinically significant anxiety and depression in outpatients. It is widely used in general medical settings and is the most frequently utilised scale in the COPD literature. A recent review exploring the prevalence of anxiety symptoms in patients with COPD found nine studies that utilised the as a screening tool for depression and anxiety [1]. The HADS has also been recommended by the ACCP [31] and GOLD (2013) for screening [43] anxiety and depression in COPD populations.

The HADS contains 14 items covering both anxiety and depression, with patients asked to recall their experiences during the past week. The anxiety component of the HADS (the HADS-A) contains seven items: three items referring to fear or panic and four items referring to generalised anxiety. Scores range from 0 to 21 for the anxiety subscale. The depression component of the HADS (the HADS-D) comprises of seven items for depressive symptoms, with scores range from 0 to 21. A major innovation in the development of the HADS was the deliberate exclusion of symptoms that might arise from the somatic aspects of illness. This ensured that the scale (in theory) is not be confounded by physical symptoms of illness or disease [67].

Zigmond and Snaith [48] originally proposed a cut-off score of ≥ 8 as a possible case of anxiety, and ≥ 11 for a definitive case. More recently, Bjelland et al. [68] and Bunevicious et al. [69] report that a score of ≥ 9 represents the optimal cut-off point for clinically significant symptoms of anxiety. However, Bunevicious et al. [69] also found that the optimal cut-off points varied depending on the type of anxiety disorder being screened. For example, the optimal cut-off point for patients with PD was ≥ 11 yet the score was ≥ 9 for phobias and GAD. Other studies have demonstrated that optimal cut-off points in older patients with COPD may be considerably lower, perhaps as low as ≥ 4 [65].

The internal consistency of the HADS is generally moderate-high with reported Cronbach's α for the anxiety subscale of 0.76–0.93 in patients with chronic disease [68]. Quintana et al. [70] demonstrated a Cronbach's α of 0.86 for both the anxiety and depression subscales. Test-retest reliability has been reported as 0.84 at two weeks, 0.73 at two to six weeks and 0.70 at >6 weeks [71].

The validity of the HADS has been extensively tested. In terms of factorial validity, the majority of studies have found a two-factor structure for the scale, corresponding to "anxiety" and "depression" [68, 70]. However, other studies have found a three-factor solution indicative of the tripartite model of anxiety and depression [72, 73].

Although there is consistent support of the HADS for the purposes of clinical screening of anxiety disorders and measurement of the severity of anxiety symptoms, there is growing concern regarding the scale's validity and reliability in populations with illness and disease [67]. In particular, Martin highlights that if the bi-dimensionality of the HADS is not supported, or found to be compromised in certain clinical populations, then the scale cannot be concluded to reliably and accurately measure the two domains of anxiety and depression. A review of the

HADS by Bjelland et al. [68] supported the use of the HADS in a range of settings (including primary care, acute care and psychiatric populations), yet only 11 of the 20 studies they review support a bi-dimensional factor structure. A more recent review that focussed on studies from the year 2000 onwards found that only seven of 22 studies report a bi-dimensional structure [67]. The majority of contemporary studies report a 3-factor structure, yet one study by Karimova and Martin [74] found that in a sample of pregnant women ($n = 100$) there were 4–5 factors underlying the HADS. In addition, even among those studies who report a bi-dimensional structure, there were a number of instances where items loaded onto the "wrong" factor [67].

State-Trait Anxiety Inventory (STAI)

The STAI [75] is a 40-item scale measuring transient and enduring levels of anxiety. The first 20 items measure situational or state anxiety with respondents asked to indicate "How you feel right now, that is, at this moment". The second 20 items refer to underlying or trait anxiety for which respondents are asked to indicate "How you generally feel". The time frame for the state questions is "right now", which may yield problems when assessing patients with PD outside the context of a PA [62]. Each item on the STAI is scored on a four-point scale and totals for the trait and state subscale range from 20 to 80.

The STAI is used frequently within the COPD research, both as an outcome measure [76] and as a screening tool [77]. It is also the most commonly used anxiety measure in contemporary medical research [55]. Reliability for the scale is generally good. McDowell [51] reviewed a number of studies exploring the internal consistency of the STAI, the majority of which were in healthy student populations, and found Cronbach's α of between 0.83 and 0.95 for the state scale and 0.67 and 0.95 for the trait scale. Predictably, test-retest scores for the state scale are lower than those for the trait scale. For example, McDowell [51] reports 30-day retest values ranging between 0.71 and 0.75 for the trait scale and 0.34–0.62 for the state scale.

To assess the validity of the scale, Vagg et al. [78] conducted a factor analytic study of the STAI and found a four-factor structure that distinguished between state and trait anxiety and between positively and negatively worded items. However, a Rasch analysis in the mid-1980s showed that a number of items on both the state and the trait scales did not meet the scaling criteria and that there was inadequate coverage at the low end of the anxiety continuum [79]. More recently, it has been suggested that the STAI is not specific to anxiety. Rather, McDowell [51] suggests that the STAI correlates more highly with depression scales than with anxiety scales such as the BAI.

Results from a FA conducted by Bieling et al. [80] suggest that the trait part of the STAI does not assess "pure" anxiety, but rather includes items that reflect depression and general negative affect. The authors found a hierarchical factor structure with a principal factor representing negative affect and two secondary factors reflecting anxiety (items representing rumination, worry and disturbing thoughts) and depression (items representing dysphoric mood and negative

self-appraisal). A more recent FA found poor fit for the two-factor model and instead proposed a five-factor model: a 10-item anxiety factor containing three related subfactors (restlessness, self-confidence and worry), a four-item unsuccessfulness factor and a six-item happiness factor [81].

Kvaal et al. [82] assessed the state subscale of the STAI in screening for anxiety disorders among stable geriatric patients. Their results suggest that the optimal cut-off score is 54/55, with a sensitivity of 0.82 and a specificity of 0.88. The STAI contains a high number of items for a self-report measure. However, Leentjens et al. [62] argue that some of the symptoms of anxiety disorders such as GAD, PD and phobias, such as fatigue, concentration and irritability, are not represented in the state scale, limiting the face and content validity of the STAI as a generic measure of anxiety.

Anxiety Inventory Respiratory Disease (AIR)

The AIR comprises 10 items, self-administered covering anxiety symptoms, with patients asked to recall their experiences during the past two weeks [83]. It is developed with a Likert type of response 0–3. Scores range from 0 to 30. The AIR is a disease-specific tool to assess anxiety in COPD patients with deliberate exclusion of symptoms that might arise from the somatic aspects of illness. It takes about 3 min to complete the scale.

The AIR has high internal consistency (Cronbach's $\alpha = 0.92$) and test-retest reliability (ICC = 0.81), and excellent convergent validity, correlating with the Hospital Anxiety and Depression Scale-Anxiety subscale ($r = 0.91$, $p < 0.001$). A cut-off score of 14.5 yielded a sensitivity of 0.93 and specificity of 0.98 for detection of clinical anxiety [84]. This is a promising screening tool to assess anxiety in patients with COPD. It is a reliable and valid scale for measuring and screening anxiety in patients with COPD. A recent study [85] examined the responsiveness of the AIR scale to eight weeks outpatient pulmonary rehabiliation (PR) program. The AIR scale was sensitive to change following PR. Change in AIR was significantly correlated to change in quality of life (using the St. Georges Respiratory Questionnaire) and dyspnoea. The effect size of AIR was 1.01 and minimal clinical important difference was 5.55.

General Limitations of the Scales

Although some extant scales have been designed specifically to omit somatic anxiety symptoms, it is evident that none have so far achieved this goal. Both the HADS and the GAI were based on a cognitive model of panic, yet results from CFAs reveal that each scale contains items that load onto somatic factors. Scales such as the BAI and STAI include somatic items in varying proportions. The BAI is heavily weighted towards measuring somatic symptoms and contains 14 somatic items out of a total of 21.

The fact that extant anxiety and depression scales measure somatic symptoms is not a problem in the majority of settings. On the contrary, somatic symptoms are key considerations for the diagnosis of a range of anxiety and depression disorders. For example, GAD is characterised by fatigue and muscle tension, whilst PD is characterised by PAs that are dominated by somatic symptoms including palpitations, breathlessness and sweating [12]. However, these anxiety symptoms mirror the common symptoms experienced by patients with COPD and may confound the diagnosis of anxiety. According to Hill et al. [86], anxiety and depression scales [86] that contain somatic items such as breathlessness and fatigue are likely to overestimate the prevalence of anxiety and depression (i.e. create false positives), since some symptoms may be associated with the primary respiratory component. Coffman (2002) adds [87] that further confusion can be caused by the side effects of medications. For example, bronchodilators used by patients with COPD can cause tremor, palpitations and insomnia, which can be associated with symptoms of anxiety. Without a formal psychiatric interview, it is difficult to establish to the cause of somatic symptoms, and therefore, scales containing somatic items may have a limited clinical utility in this population.

In an effort to distinguish between anxiety and depression, the BAI focus upon symptoms which are specific to anxiety. In addition, the BAI focuses upon psychophysiological symptoms of anxiety which can help to distinguish between anxiety and depression. The scale focuses upon symptoms of hyperarousal such as inability to relax, heart palpitations and tremor. Subsequently, those patients with high levels of cognitive anxiety may be underrated, whilst those exhibiting high levels of somatic symptoms may be overrated [51].

The strong correlations between BAI and depression scale means that it is likely that there is a common underlying negative factor. Therefore, it is impossible to separate anxiety and depression completely [51]. It is possible, however, that efforts to discriminate between anxiety and depression have resulted in scales that do not cover the full range of anxiety symptoms. For example, Cox et al. [61] argue that the somatic-dominated BAI represents somatically laden panic rather than more general (cognitive) symptoms of anxiety. It is posited that both the DASS and the BAI measure symptoms of the majority of anxiety disorders with the exception of GAD [51].

Scales such as the HADS appear to cover a more general range of symptoms, including items relating to fatigue and irritability, but this can lead to cross-loading between anxiety and depression factors. Factor analysis of the HADS demonstrates that there is a general negative affect factor underlying the scale and this, in theory, may limit the specificity of the HADS for detecting and discriminating between anxiety disorders and depression.

Validation in Patients with COPD

Perhaps the most important limitation to the clinical utility of existing anxiety and depression scales is that few have been validated in patients with COPD. This is an

especially important consideration as scales may perform very differently between clinical populations and identical item/scale performance cannot be assumed between groups [88]. For example, the majority of extant anxiety scales were developed for general use, e.g. HADS for use in medical outpatients.

Of the six scales that have been recommended for use, or are frequently used in patients with COPD, only the BAI, GAI and the HADS have been validated (in a limited fashion) in this patient group [36, 65]. However, no studies have specifically sought to explore the reliability or validity of these anxiety scales in patients with COPD. Cheung et al. (2012) and Kunik et al. (2005) have explored [36, 65] the ability of the GAI, HADS and BAI to screen for the anxiety disorders in patients with COPD. The AIR is a new scale that has been developed for screening anxiety for patients with COPD. It is quite a promising tool. However, its clinical utility and responsiveness to intervention has not been tested for patients with COPD.

Although the HADS is recommended by NICE and AACP guidelines and is likely to be the most commonly used scale among clinicians and researchers working with patients with COPD, Cheung et al. (2012) suggest [65] that there is sufficient doubt in its ability to screen anxiety disorders accurately in older populations (particularly those with COPD) for it not to be recommended for clinical or research purposes.

Summary

It is clear that although all of the scales reviewed have promising reliability and validity in general medical populations, or in the populations they were designed for, few, with the exception of the AIR, BASDEC, BAI, GAI and HADS have been partially validated in patients with COPD. The ability of these three scales to screen for clinical anxiety and depression in patients with COPD demonstrates that none has particularly high sensitivity. In addition to the lack of validation in patients with COPD, all of the scales reviewed have limitations in one or more key areas, including the inclusion of somatic items, selective symptom coverage and questionable factorial validity. The AIR scale was responsive following PR in short term. However, its efficay in long-term follow-up is unknown. Therefore, further work is needed to validate a disease-specific anxiety and depression scales for patients with COPD.

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