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Use of the patient care monitor to screen for depression in adult cancer patients interviewed with the structured clinical interview for DSM-IV

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Abstract

***Objective*: To evaluate the Patient Care Monitor (PCM1.0) Acute Distress and Despair normalized *T* scores as indicators of a diagnosis of Major Depression according to the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID).**

***Methods*: Subjects were 21 adult cancer patients identified by treating community oncologists as having significant emotional distress matched on age, cancer type, treatment history, and sex to 21 patients not having significant distress. All completed e/tablet PCM 1.0 and SCID administered by trained interviewers. Unweighted kappa and receiver operating characteristics (ROC) analyses were used to assess scale properties.**

***Results*: Agreement between SCID Major Depression and Acute Distress and Despair ($T \geqslant 65$) were kappa = 0.751 and 0.755, respectively. ROC area under the curve values for these two scales were 0.967 (SE $\pm$ 0.03) and 0.942 (SE $\pm$ 0.03), respectively, with optimal cut points of $T = 61$ and 63, respectively.**

***Conclusions*: Under conditions of preselected extreme groups, PCM 1.0 Acute Distress and Despair *T* scores are reasonable screening indicators of clinical depression in cancer patients. PCM 1.0 provides an efficient method for point-of-care screening of depression in community oncology clinics.**

Keywords: cancer; oncology; depression; anxiety; DSM-IV; ROC analysis

Objective

Cancer patients often experience psychological difficulties, including sadness, grief, anxiety, irritability, guilt, sleep disturbance, and poor concentration. Although the majority manages their symptoms adequately, some experience significant difficulties that may interfere with medical treatment [1]. Prevalence rates of depression have been difficult to estimate due to variations associated with screening methods, disease characteristics, and patient age [2]. Coyne and his colleagues reported that 9% of breast cancer patients met diagnostic criteria for Major Depression when structured clinical interviews were used [3]. This is slightly higher than the 12 months general population prevalence rate of 6.6% [4]. Interview-based estimates of anxiety disorders suggest that such problems occur in about 7% of cancer patients, and it is not uncommon for both problems to be present in the same patient [2]. Because of the potential for negative impact on quality of life (QoL) and delivery of medical treatment, it is important to screen for such problems.

Efficient and effective screening for clinical depression and anxiety is complicated by the fact that it is normal for cancer patients to have higher than average levels of distress. Routine use of measures that primarily assess severity of distress as compared with normal or even mental health service seeking populations can over identify problems in cancer patients [5]. Measures are needed that compare cancer patients to a normative group of cancer patients.

Another difficulty is the strong correlation between measures of depression and anxiety. If a set of questions measures generalized distress or undifferentiated negative emotion, as most do, then it will fail to discriminate between Major Depression and anxiety disorders. This necessitates further action to make the distinction. Clark and Watson have noted that the key to differentiation is to have some measure of positive affect. This permits one to identify loss of positive affect among depressed

patients and to distinguish that feature from physical tension and hyper arousal, which is the most prominent feature of anxiety [6].

Several instruments have been developed to address the challenge of evaluating psychological difficulties in cancer patients. Much of this work has advocated for a primary focus on undifferentiated emotional distress [7]. The Distress Thermometer (DT) was developed as a single item indicator of undifferentiated distress [8]. Currently, the National Comprehensive Cancer Network recommends that the DT be administered along with a 35-item list of problems [9]. This adds important detail but also undermines the brevity of the instrument, a factor that is important in how acceptable a physician will find an instrument for routine use [10].

To use technology to support brief and efficient questionnaire administration, researchers have promoted the use of e/tablet computers [11–14]. This enables patients to report their symptoms while waiting for their physician and simultaneously reduces staff workload through automated scoring and report generation. Quality of life assessment via e/tablet can also eliminate problems with omitted or invalid item responses and has been found to be a reliable method of assessment [14]. Furthermore, screening measure completion through e/tablet computers has been reported to be an easy task for patients, even when they are beginner level computer users [11,12].

The Patient Care Monitor 1.0 (PCM 1.0; formerly called Cancer Care Monitor) is an assessment tool designed to be integrated into clinical practice through use of pen-based e/tablet computers that collect, analyze, score, summarize, and deliver patient-reported outcomes to clinicians within minutes [15,16]. The PCM 1.0 comprises six primary symptom scales and one global QoL index. By providing a means to track the scores of patients over time, physicians are better equipped to take preventative steps with high risk patients and to monitor patients. In a preliminary study of the PCM 1.0, the Acute Distress and Despair scales were strongly associated with a validated measure of psychological distress in cancer patients [16]. Accordingly, the Acute Distress and Despair scales of the PCM 1.0 may be useful tools to screen for cancer patients who are likely to be suffering from Major Depression.

The objective of this study was to evaluate the Acute Distress and Despair scales of the PCM 1.0 as practical screening procedures to identify clinical depression in cancer patients who were selected to be at either high or low risk for depression as judged by their medical oncologists. In this study, the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID) served as "the gold standard" for the diagnosis of psychiatric disorder [17].

Methods

Participants

Participants were ($N = 42$) volunteer adult cancer patients recruited from 1 January 2001 to 31 May 2002 from a large oncology practice, West Clinic, Memphis, TN. West Clinic serves patients with a wide variety of cancer types, but breast cancer is predominant, accounting for approximately 60% of cases. Participants' demographic characteristics are reported in detail below. Patients who agreed to participate were provided with a brief explanation of the purpose of the study and the rights of participants. All participants signed informed consent forms approved by the University of Memphis Institutional Review Board. All were paid $25.00 for their participation. Research staff and medical staff were integrated into the clinic and trained in HIPAA procedures. All patients were informed about the practice of communication between clinical and research staff and gave permission for such protected communication.

Design and procedures

For this study, two samples were recruited. Recruitment for both samples took place concurrently. In order to create an expedited sample of patients who were likely to suffer from clinically significant distress, the recruitment procedure relied on referrals from physicians. Referrals were requested at three different meetings, where physicians were asked to identify patients they thought were more depressed than nervous, as well as contrasting patients who they thought were likely to be free from significant emotional distress. The first group ($n = 21$) comprised patients identified by their oncologist as likely to be suffering from significant emotional distress. Physicians were informed about the approval for the study and were asked to work with research staff to introduce the purpose of the study and to facilitate contact with the research staff when a prospective patient indicated interest. Treating physicians made the initial contact with the patient. With such direct physician involvement, only three prospective participants declined the invitation to be in the study after the patient met with the research staff.

The second sample of patients ($n = 21$) was collected as a comparison group and consisted of individuals who were likely to be free from significant emotional distress. This group was matched to the first group on several key variables including age, cancer type, treatment history, and sex. Prospective patient volunteers from this group were identified by appointment records to determine match on key variables, and their physicians were then contacted to assist with introducing the study. Similar to procedures used to recruit the first group, patients' physicians were contacted to

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determine whether the individuals appeared to be free of any significant emotional distress. From this subject recruitment process, nine patients refused to participate in the research.

Those agreeing to participate in the study completed the electronic tablet computer administered (e/tablet) version of the Patient Care Monitor as well as an identifying information form. Average completion time for the PCM 1.0 was under 3.5 min, with first time use slightly longer at less than 5 min. As might be expected, introduction to the PCM 1.0 requires some brief acculturation, but no significant difficulties completing the measure were reported. Following this, advanced doctoral students in clinical psychology, who had been trained to administer the SCID, conducted SCID interviews with all participants. These interviews typically lasted approximately 45 min to 1 h for patients who endorsed many symptoms. Because the SCID is hierarchical and permits skipping of items, interviews with patients who endorsed no symptoms typically lasted less than 20 min. Interviewers were not informed of the status of the patient being interviewed. Participants in both the groups completed the forms and the SCID interview in the same order.

Five advanced graduate students in clinical psychology completed approximately 100 h of intensive training in the SCID interview procedure. Training also emphasized identification of cancer disease and treatment-specific conditions that might lead to diagnosis of an Axis I disorder attributable to a general medical condition. Interviewers consulted treating oncologists and nurse practitioners whenever such questions arose. Role play was used to assess inter-rater reliability during practice sessions, and raters were trained to a criterion of kappa for Axis I diagnosis $\geqslant 0.85$.

As a further check on inter-rater reliability, we randomly selected five cases from each group to have a second interviewer present during the SCID. The second interviewer only interacted with the patient if he or she needed clarification for a specific patient response beyond that elicited by the primary interviewer. Paired interviewers were seated so that they could not observe how each was completing the paper version of the SCID protocol.

Measures

Identifying information

Participants provided basic background and demographic information, such as date of birth, sex, diagnosis, date of diagnosis, marital status, ethnic background, level of education completed, and household income. Research assistants reviewed medical charts to verify date of birth, medical diagnosis, date of diagnosis, stage at diagnosis, and treatment received.

Patient care monitor (PCM 1.0, formerly called cancer care monitor [CCM])

PCM 1.0 comprises 38 patients reported outcome items that are administered serially on a touch screen-based tablet computer as illustrated in Figure 1. Each item is presented so that the patient rates the degree to which the item has been a problem in the past week using a 0–10 scale of severity (0 not a problem to 10 as bad as possible). The instructions are: 'Touch the red dot on the line that best describes how bad the symptom has been for you during the past week including today'.

PCM 1.0 was validated in comparison with a series of symptom and health-related QoL measures [16] including: Brief Symptom Inventory [18], Medical Outcomes Study SF-36 Health Survey (SF-36) [19,20], Memorial Symptom Assessment Scale [21], Life Satisfaction Index-Short Form [22,23], and Satisfaction with Life Scale [24,25]. PCM 1.0 yielded six scales: General

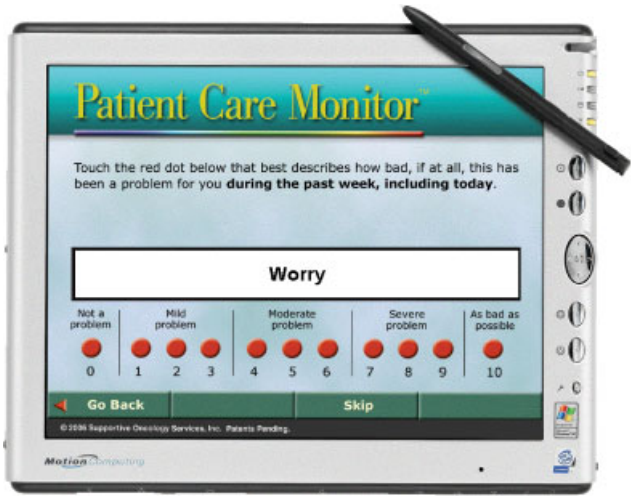

Figure 1. Patient Care Monitor (PCM 1.0) item for fatigue (tiredness) with response scale presented on e/tablet

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Physical Symptoms (11 items), Treatment Side Effects (8 items), Acute Distress (4 items), Despair (7 items), Impaired Ambulation (4 items) Impaired Performance (4 items). The internal consistency reliabilities ranged from 0.80 to 0.89 (Cronbach's alpha). In addition to the six scales PCM 1.0 also yielded an overall health-related QoL Index. Each of the six scales and QoL Index can be reported as normalized *T* scores (Mean 50, SD 10) based on a standardization sample of 449 adult cancer patients. The pattern of concurrent validity coefficients supported the validity of the six scales and QoL Index of the PCM 1.0 [16]. The present study used only the acute distress and despair subscales.

A unique feature of the PCM 1.0 scale sores is that they can be expressed as normalized *T* scores with a mean of 50 and standard deviation of 10. The normative group consisted of 449 diverse cancer patients who participated in the psychometric validation study of the PCM 1.0 [16]. This method of scale construction means that a *T* score greater than or equal to 65 places the individual at the 95th percentile or above relative to the reference group of heterogeneous cancer patients. A *T* score $\geqslant 65$ on Acute Distress or Despair means that the individual with that score falls at the extreme end of a normalized distribution of scores relative to cancer patients. The PCM 1.0 Acute Distress and Despair scales were designed to assess anxiety and depression with specific reference to cancer patients as the normative group.

The PCM 1.0 is also acceptable to patients and economically sound for physicians. With regards to patient acceptability, a key to compliance is having their physician endorse and then use the measure during visits. For patients who know that their physician will use the measure, compliance is well above 95%. With regards to economic feasibility, the current version of the PCM (PCM 2.0, Acute Distress and Despair scales unchanged) has shown an ability to pay for itself within 2 years. PCM results can supplement documentation of a full review of systems, which permits physicians coding for a higher level visit.

Structured clinical interview for DSM-IV axis I disorders (SCID)

The SCID is a structured clinical interview to determine psychiatric diagnoses for Axis I of the Diagnostic and Statistical Manual of Mental Disorders (DSM) fourth edition [26]. It is regarded as the gold standard for mental health diagnosis. The SCID is administered hierarchically; if an item is endorsed, the interviewer seeks additional details. If an item is not endorsed, the interviewer moves forward to subsequent items. A specially modified version of the SCID, the SCID Non-Patient edition, designed for research with primary care populations was used for cancer patients in a primary medical setting [17,27]. The SCID was designed in modules to be modified for specific purposes of a study. The modules of the SCID used in the present study were: Screener items for drug and alcohol abuse (1 page), Mood Episodes (46 pages), Psychotic Screener (3 pages), Mood Differential (11 pages), Adjustment Disorder (2 pages), Acute Stress Disorder (7 pages), and Anxiety Disorders (41 pages). Altogether, this version of the hierarchical, research-based SCID covered a total of 521 possible questions.

Statistical analyses

To check comparability of basic demographic information from the matching procedures used for groups, we conducted *t*-tests for continuous variables and chi square tests for categorical variables. Inter-rater agreement using unweighted kappa for Axis I diagnosis was computed for the subsample of patients where there were two interviewers present for the SCID administration. Unweighted kappa was also computed for the categorical agreement for the presence or absence of anxiety disorder or mood disorder as determined by SCID versus, respectively, PCM 1.0 *T* score $\geqslant 65$ on the Acute Distress or Despair scales. We also used receiver operating characteristics (ROC) analysis to examine different *T* score cut points on the Acute Distress and Despair scales to maximize sensitivity and specificity under the assumption that the SCID determination of the presence or absence of disorder was the gold standard for diagnosis.

Results

Table 1 shows demographic characteristics of the two patient groups. Referrals for the study came from five different physicians. Analysis of patient demographics and disease characteristics by physician showed no significant differences among patients according to referring physician.

As might be expected from matching procedures, there were no statistically significant differences between the groups on demographic descriptors (all p's > 0.20). Patients were predominantly female with average age of 55 years old. They were also predominantly Caucasian/Not Hispanic with a small minority of African Americans, and over 90% reported education at or beyond high school graduation. Over three fourths were married, and over half reported annual household incomes above $30 000. Table 1 also shows disease-related characteristics for the two groups. Patients in both samples had a variety of cancer diagnoses, with breast cancer the largest proportion followed by lymphoma. A majority in both groups had not received treatment in the immediate preceding

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Table 1. Demographic, disease, and previous treatment characteristics of matched adult cancer patients identified by treating oncologists as either having or not having significant emotional distress

	Patients with distress ($n = 21$)	Patients without distress ($n = 21$)
Mean Age in years (range)	53.0 (21–80)	57.0 (32–81)
Female	71.4 %	76.2 %
Ethnic background		
Black/African American	9.5	19.0
American Indian/Alaskan Native	0.0	4.8
Caucasian/Not Hispanic	90.5	76.2
Education ⩾12 years	90.5	100.0
Marital status		
Married	76.2	81.0
Single	9.5	9.5
Divorced	14.3	—
Widowed	—	9.5
Household income[a]		
Under 15K	10.0	15.8
15–29 999K	20.0	10.5
30–49 999K	25.0	15.8
50–74 999K	20.0	36.8
75–99 999K	10.0	10.5
100–149 999K	15.0	5.3
Over 150K	—	5.3
Cancer type		
Breast	38.1	38.1
Gastrointestinal	14.3	14.3
Lung	9.5	9.5
Lymphoma	23.8	23.8
Other diagnoses	14.4	14.4
Treatments in past 3 months		
Surgery	0.0	4.8
Chemotherapy	33.3	19.0
Radiation	4.8	14.3
Hormonal therapy	4.8[a]	10.5[a]
None in past 3 months	61.9	65.0[a]

Note. Values are percentages unless otherwise designated. Patients in the 'without significant emotional distress group' were matched to patients in the 'with significant emotional distress group' on the following characteristics: age, cancer type, treatment history, and sex.
[a]One participant did not provide information.

3 months, and among those who did, chemotherapy was the most frequent of recent treatments. Again as would be expected from matching procedures, there were no significant differences between the two samples on types of cancer and previous treatment (all p's > 0.20).

SCID results

To assess inter-rater reliability, we randomly selected 25% of the SCID administrations ($n = 5$ for each group) for a reliability check. These administrations were conducted with two interviewers present, with one acting as the primary interviewer and the second participating only when necessary to clarify patient responses. The unweighted kappa obtained for the Axis I diagnoses was 1.0.

None of the patients in the group selected by their physicians as being free of significant emotional distress met criteria for an Axis I diagnosis based on the SCID administration. Table 2 shows the Axis I diagnoses of the 21 patients identified as having significant emotional distress. Of the 21, 19 (91%) met criteria for Major Depression, but among those, 2 were diagnosed as in full remission from a previous episode. Therefore, in subsequent analyses only 17 of the 21 patients from this group were treated as meeting SCID criteria for current Major Depression. As shown in Table 2, two patients received primary diagnoses other than depression, one for Opioid-Induced Mood Disorder, and another for Generalized Anxiety Disorder. Also among the 8 patients with a primary diagnosis of Major Depressive disorder, recurrent, and severe, 4 (19%) had a dual diagnosis of an anxiety disorder (Generalized Anxiety Disorder, Panic Disorder with Agoraphobia, Panic Disorder without Agoraphobia and Obsessive–Compulsive Disorder), and one patient among those 4 also met

Table 2. Number of Axis I disorders diagnosed from the Structured Clinical Interview for DSM-IV Axis I disorders 21 cancer patients identified by treating oncologists as having significant emotional distress

Primary diagnosis	*n*	Second diagnosis	Third diagnosis
Major depressive disorder, recurrent		Generalized anxiety disorder	
Severe without psychotic features (296.33)	8	Panic disorder with agoraphobia	
Major depressive disorder, single episode		Panic disorder without agoraphobia	Social phobia
Severe without psychotic features (296.23)	4	Obsessive compulsive disorder	
Major depressive disorder, single episode			
Moderate (296.22)	3		
Major depressive episode, single episode			
in Full Remission (296.26)	2		
Major depressive episode, recurrent,			
Mild (296.31)	1		
Major *depressive episode, recurrent,*			
Moderate (296.32)	1		
Opioid-induced mood disorder (292.94)	1		
Generalized anxiety disorder	1		

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criteria for a diagnosis of Social Phobia. With only one case given a primary diagnosis of anxiety disorder in this sample, we focused additional analyses on Major Depression only.

PCM 1.0 acute distress and despair related to SCID diagnosis

We examined the commonly used cut points of normalized T scores $\geqslant 65$ for Acute Distress and Despair scales of the PCM 1.0 for agreement with mood disorder diagnoses based on SCID interviews. Considering the 17 cases of SCID identified current Major Depression, unweighted kappas were: Acute Distress, 0.751 and Despair, 0.755.

ROC analysis

We used ROC analysis of the overall sample ($N = 42$) to examine various T score cut points of the Acute Distress and Despair scales as accurate indicators of current Major Depression determined by the SCID. ROC analysis produces a range of cutoff scores from the minimum observed value to the maximum observed test value. For each cutoff value, the ROC curves plot true positive rate (sensitivity) on the y-axis against the false positive rate (1-specificity) on the x-axis to produce a plot showing how well the test separates the participants into those with or without a diagnosis. To assess the accuracy of the measure, the ROC analysis produces a statistic called area under the curve (AUC), which ranges from 0 to 1. An AUC of 0.50 represents diagnostic performance equal to chance and AUC of 1 represents perfect diagnostic performance. Figures 2(a) and (b) show the ROC curves, respectively, for the Acute Distress and the Despair scales. The AUC for Acute distress was 0.967 (SE+0.03) and for Despair was 0.942 (SE+0.03).

We also used ROC analysis to identify specific cutoff scores for both the Acute Distress and Despair subscales as shown in Table 3. To identify the point where sensitivity and specificity were both maximized, we calculated Youden's Index [28]. The highest Youden Index for the Acute Distress was 0.84, corresponding to a T score of 61, and for Despair the index was 0.78, corresponding to a T score of 63.

Conclusions

This study provided an initial examination of the utility of the PCM 1.0 as a brief, easily administered screening tool to identify possible cases of clinical depression in cancer patients who were selected to be at either high or low risk for clinical depression. PCM 1.0 Acute Distress and Despair scales were designed to measure anxiety and depression with specific reference to cancer patients as the normative group. Under these ideal conditions of patient selection, ROC analysis showed that normalized T scores greater than 61 and 63, respectively, for Acute Distress and Despair can accurately discriminate patients who received a diagnosis of Major Depression from those who did not. Using the conventional T score cutpoint of 65 or greater, chance adjusted agreement between SCID diagnosis and scale scores exceeded 0.70, a threshold generally regarded as acceptable to good [29].

Previous psychometric research has suggested that while the Acute Distress and Despair scales are highly correlated ($r = 0.70$), they also may emphasize different aspects of psychological distress, anxiety and depression, respectively [16]. However, within the current study the two scales did not show evidence for differential discriminant ability to screen for Major Depression. Surprisingly, the Acute Distress scale was a slightly better indicator of Major Depression than the Despair scale. This may have been due to the small sample size and the fact that among the few patients who did receive an anxiety-related diagnosis most also received a dual diagnosis of Major Depression. Depending on the context in which the PCM 1.0 is used, this may not be problematic. The appropriate role of a brief screening instrument is to identify which patients warrant further attention in the form of clinical interview. Accordingly, it would be unwise to assume that the PCM 1.0 scales can be used to make accurate differential diagnosis.

The situation is likely to arise in which a patient scores above the cutoff score on one of the scales, but not the other. Accordingly, it is appropriate to consider the appropriate course of action in this situation. Because both the Acute Distress scale and the Despair scale are shown to have the ability to screen for possible cases of Major Depression, it is advisable to follow up with a clinical interview when a patient has exceeded the cutoff score for either of these scales. Owing to the significant impact of Major Depression on a patient's life, this extra caution is warranted. Future research may allow for greater discrimination to be made in the decision-making process.

A major limitation of the current sample was that it represented extremes of psychological difficulty among the general cancer population. Additionally, the study included primarily Caucasian females. It remains for further research to determine how well the PCM 1.0 Acute Distress and Despair scales will perform in unselected and more diverse samples of adult cancer patients. Future research should expand the scope of the present study by determining the sensitivity and specificity of the scales using a larger sample of patients who have not been pre-screened for psychological distress. Such analyses should also be conducted across clinical characteristics such as

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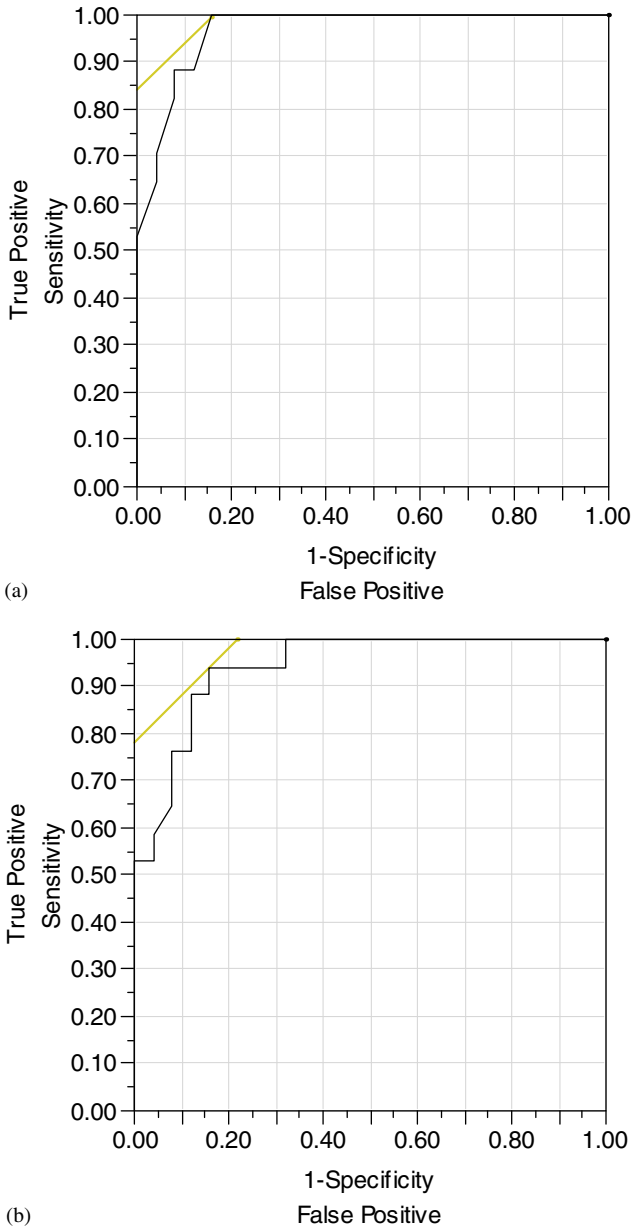

Figure 2. Receiver operating characteristic curves of the PCM 1.0 acute distress: (a) despair and (b) scales to detect current major depression from structured clinical for DSM-IV Axis I disorders among 42 select adult cancer patients

type and stage of cancer, treatment modality, and presence of metastasis.

Whereas matching strategies were used across groups, it is important to recognize that it is not possible to control for all of the potentially important differences that inevitably exist between these groups. Some important differences that were not controlled include: prior psychiatric history, social and family support, and financial circumstances. Because more than half of the 21 patients in the distressed group were found in retrospect to have had a history of a psychiatric disorder (i.e. 10 patients were diagnosed with recurrent MDD, 2 patients were diagnosed with MDD in full remission), the present study must be regarded as from an atypical sample of cancer patients with a history of psychiatric disorders.

It should be noted that the current study suffered from the small sample size. Accordingly, limitations in statistical power do exist. As a result, it is possible that we were unable to detect differences between the sample groups that could have had an effect on the primary results (e.g. differences in ethnic makeup and chemotherapy administration). In order to address the present limitation, future research will need to enlist larger, more representative samples.

The field of psycho-oncology has struggled with the problem of screening for psychological difficulties with cancer patients. This has largely stemmed from the shortage of instruments that have been designed and normed specifically for use with cancer patients. The PCM 1.0 Acute Distress and Despair scales offer a cancer patient-specific

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Table 3. Receiver operating characteristics T score cut points for optimum sensitivity and specificity using PCM 1.0 acute distress and despair scales to identify cancer patients with current major depression determined by Structured Clinical Interview for DSM IV Axis I Disorders

T score cut point	1 Minus specificity	Sensitivity	Youden's Index	True positive	True negative	False positive	False negative
Acute Distress Scale							
65.56	0.08	0.82	0.74	14	23	2	3
64.36	0.08	0.88	0.80	15	23	2	2
63.61	0.12	0.88	0.76	15	22	3	2
61.03	0.16	1.00	0.84[a]	17	21	4	0
59.59	0.24	1.00	0.76	17	19	6	0
58.21	0.28	1.00	0.72	17	18	7	0
57.26	0.32	1.00	0.68	17	17	8	0
Despair Scale							
65.59	0.12	0.82	0.70	14	22	3	3
64.71	0.12	0.88	0.76	15	22	3	2
63.71	0.16	0.88	0.72	15	21	4	2
62.96	0.16	0.94	0.78[a]	16	21	4	1
61.43	0.24	0.94	0.70	16	19	6	1
60.80	0.28	0.94	0.66	16	18	7	1
60.22	0.32	0.94	0.62	16	17	8	1

[a]Optimal T score cut point indicated by maximum value of Youden's Index.

approach to screening for potential cases of depression. Additional inquiry is required to assess for the ability of these scales to detect possible cases of anxiety.

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