# **ORIGINAL ARTICLES**

# Screening for psychological distress in two French cancer centers: Feasibility and performance of the adapted distress thermometer

SYLVIE DOLBEAULT, m.d.,<sup>1,2,3,4</sup> ANNE BREDART, ph.d.,<sup>1,5</sup> VÉRONIQUE MIGNOT, ph.d.,<sup>1</sup> PATRICK HARDY, m.d.,<sup>2,4,6</sup> ANNIE GAUVAIN-PIQUARD, m.d.,<sup>7</sup> LAURENCE MANDEREAU, m.d.,<sup>8</sup> BERNARD ASSELAIN, m.d.,<sup>8</sup> and

JACQUES MEDIONI, M.D.<sup>8</sup>

<sup>1</sup>Unité de Psycho-Oncologic, Départment Interdisciplinaire de Soins de Support pour le Patient en Oncologie, Paris cedex, France

<sup>2</sup>Université Paris-Sud, Paris, France

<sup>3</sup>Université Paris V, Paris, France

<sup>4</sup>INSERM, Paris, France

<sup>5</sup>Laboratoire de Psychopathologie et Neuropsychologie clinique, Université Paris V, Paris, France

<sup>6</sup>AP-HP, Le Kremlin-Bicêtre, Paris, France

<sup>7</sup>Unité de Psycho-Oncologie, Institut Gustave Roussy, Villejuif, France

<sup>8</sup>Service de Biostatistiques, Institut Curie 26, Paris cedex, France

(RECEIVED September 16, 2007; ACCEPTED October 16, 2007)

# ABSTRACT

*Objective:* Little is known about the prevalence of psychiatric disorders in French cancer patients. This study aimed to assess the feasibility of a screening procedure using the Psychological Distress Scale (PDS). The PDS is a French adaptation of the National Comprehensive Cancer Network Distress Thermometer. The screening performance of the PDS was assessed by comparison with the established clinical case threshold on the Hospital Anxiety and Depression Scale (HADS).

*Methods:* Among 598 consecutive cancer outpatients recruited in two cancer centers in Paris, 561 (94%) agreed to complete the PDS, the HADS, the European Organisation for Research and Treatment of Cancer core quality of life questionnaire (EORTC QLQ-C30), and study-specific psychosocial questions.

*Results:* A receiver operating characteristic (ROC) analysis was performed, using a HADS cutoff score of 15 or greater to identify patients with psychological distress. This yielded a PDS cutoff score of 3, giving 76% sensitivity and 82% specificity. With this cutoff score, the prevalence of psychological distress was 38%. PDS scores were significantly related to scores from the HAD total scale (r = .64), HAD anxiety (r = .61) and HAD depression (r = .39) subscales, and EORTC QLQ-C30 emotional functioning (r = .56) and global health state (r = .44). In multivariate analyses, factors associated with psychological distress were female gender, taking analgesics, receiving professional psychological help, perceived psychosocial difficulties and lack of social support.

Significance of results: Using the PDS appeared feasible, acceptable and effective for psychological distress screening in French ambulatory cancer care settings.

**KEYWORDS:** Cancer, Psychological distress, Quality of life, Screening tool, Psychometric performance

#### INTRODUCTION

A diagnosis of cancer may considerably affect a patient's psychological well-being; this, in turn, may impact on treatment tolerance and outcomes,

Address correspondence and reprint requests to: Sylvie Dolbeault, Unité de psycho-oncologie, Institut Curie, 26 rue d'Ulm, 75248 Paris cedex 05, France. E-mail: sylvie.dolbeault@ curie.net

prolonging medical management and increasing health care costs. Different studies conducted in recent decades have revealed that pathological levels of distress were highly prevalent in oncology: Figures range from 5% to 50%, depending on disease-related characteristics and modes of treatment, but also on assessment procedures (Keller et al., 2004).

Health care providers often fail to recognize cancer patients' psychological distress (Passik et al., 1998; Fallowfield et al., 2001; Söllner et al., 2001, 2004; Maguire, 2002). Various explanatory factors, such as the clinical time available and the clinicians' skills or motivation, have been suggested. As a result, referral to psychological providers occurs mainly when the patient is severely anxious or depressed. Screening programs have thus been implemented to enable health care providers to identify patients who are at higher risk of psychological morbidity in order to initiate clinical interventions earlier and so prevent severe psychological disorders during the course of the illness (Zabora, 1998). Such procedures are intended to enhance health care outcomes, preserve patients' quality of life, and improve their satisfaction with care. Alongside survival, these care objectives have been recognized as an integral part of the global care contract.

Structured clinical interviews or self-reported measures have been developed to screen for psychological distress at critical stages in the course of the disease. Given the heavy workload of oncology clinics and the ever shorter hospital stays, methods for psychological screening must be brief and pragmatic (a single global score without any additional information may be sufficient to allow for the identification of the parameters of interest and for classification purposes). A number of well-validated measures exist that can be used as screeners, including the Hospital Anxiety and Depression Scale (Zigmund & Snaith, 1983), the Brief Symptom Inventory (Derogatis et al., 1983; Derogatis, 2000) or the General Health Questionnaire (Goldberg, 1978). However these instruments require time to administer, which may prevent their systematic use in the routine care of busy oncology clinics.

The Distress Thermometer (DT; Holland, 1997; National Comprehensive Cancer Network, 2003) is a brief and simple tool that has proved acceptable and useful in prostate cancer patients (Roth et al., 1998) and more recently in bone marrow transplant patients (Trask et al., 2002; Ransom et al., 2006), in mixed cancer populations (Hoffman et al., 2004; Jacobsen et al., 2005) as well as in culturally diverse cancer patient populations (Akizuki et al., 2003; Gil et al., 2005; Ozalp et al., 2007). In these studies, the DT was compared to the Hospital Anxiety and Depression Scale (HADS; Trask et al., 2002; Akizuki et al., 2003; Gil et al., 2005; Jacobsen et al., 2005; Ozalp et al., 2007), to the brief symptom inventory (BSI) (Hoffman et al., 2004; Jacobsen et al., 2005), and to the center for epidemologic studies depression scale (CES-D) and state-trait anxiety inventory-state (STAI-S) (Ransom et al., 2006), demonstrating acceptable convergent, divergent (Hoffman et al., 2004) or criterion validity (Ozalp et al., 2007), as well as measurement accuracy, with a cutoff score of 4 or 5 leading to optimal sensitivity and specificity (Roth et al., 1998; Akizuki et al., 2003; Jacobsen et al., 2005; Ransom et al., 2006; Ozalp et al., 2007).

The DT is a visual one-item self-report distress tool using the representation of a thermometer. This was selected, in the context of cancer, by analogy with indicators of individuals' physical functioning such as temperature and more recently visual analog scales for pain. Distress could be another useful indicator, because mental well-being and good spirits may play an important role in health (National Comprehensive Cancer Network, 2003; Bultz & Carlson, 2006; Holland et al., 2007).

This study aims to assess the feasibility of a psychological distress screening procedure in two cancer centers in France as well as to evaluate the sensitivity and specificity of a French adaptation of the Distress Thermometer (called the Psychological Distress Scale [PDS]), in comparison with the HADS, using the established clinical threshold in cancer patients. From responses from a large sample of cancer outpatients (n = 561), receiver operating characteristic (ROC) analyses are used to determine the ability of the PDS to distinguish cancer patients with clinically significant distress from those without, based on the previously established HADS cutoff score of 15. In addition, the relationships between psychological distress and measures of quality of life and psychosocial difficulties are also explored.

# **METHODS**

# **Participants**

Between May and November 2000, 598 patients aged 18 and over, with a confirmed histological diagnosis of cancer, with no major unstable medical or psychiatric condition, able to read and speak standard French, and attending the outpatient oncology clinic in Institut Curie (n = 335) or Institut Gustave Roussy (n = 226) in Paris, France, were approached. At inclusion, patients were stratified according to site of cancer diagnosis (breast, gynecological, brain, ophthalmic, lung, prostate, head and neck, and other cancer diagnoses). Among these, 37 patients refused to participate, 24 because they felt too "stressed," did not want to talk about psychological reactions, or found the study irrelevant, 9 because they felt too tired or presented a hearing impairment, headache, or difficulty understanding; 4 other patients because they found the questions inappropriate, had to be seen immediately by the doctor, or declared they were not available.

# Procedure

Eligible patients were contacted by a clinical research associate who introduced them to the objectives and procedure of the study. Upon agreement and after providing informed consent, patients were handed the PDS, the HADS, the European Organisation for Research and Treatment of Cancer core quality of life questionnaire (EORTC QLQ-C30), and a sociodemographic and psychosocial form to complete while waiting to see their oncologists. Conditions of confidentiality were ensured in the waiting rooms.

# **Data Collected and Measures**

For all patients, medical data (type of cancer site, phase of illness, extent of the disease, type of treatment, analgesic use), sociodemographic data (age, gender, marital status, educational level, professional status), and psychosocial information (open-ended questions on psychological treatment, psychosocial difficulties, and social support) were collected from the medical files.

#### Psychological Distress Scale

The PDS is derived from the Distress Thermometer (National Comprehensive Cancer Network, 2003). In its original English language presentation, this scale shows a thermometer graduated from 0 (no distress) to 10 (severe distress) (graduation visible for the patient), enquiring about the patient's distress in the past 7 days. Pilot testing the National Comprehensive Cancer Network (NCCN)-developed DT with health care providers in France led to modifying the layout of the tool. Quantifying psychological distress was found not to be well accepted, especially using a picture of a thermometer, because this is associated with biological parameters. As a result, the visual device used in this tool was changed to a 10-cm vertical line.

The word "distress" was chosen by the NCCN to soften the perceived social stigma associated with psychopathological labels and thus favor spontaneous disclosure of any psychological suffering experienced by cancer patients. The French literal translation of the term "distress" does not have the same connotations as the English word. In French, the word "distress" could be translated by the words "détresse," "souffrance," "désarroi," or even "difficulté" with or without the accompanying adjective "psychologique." Although the word "détresse" includes ideas of severe suffering, danger, fear of death, and need for help (while in English a subject can feel "distress" about relatively trivial things too), conciliation discussions between clinicians specialized in psycho-oncology finally led to selecting this word, but including a reference to the psychological state ("détresse psychologique").

### Hospital Anxiety and Depression Scale

The HADS is a 14-item self-report scale developed for medical patients, assessing anxiety (HAD-A) and depression (HAD-D) (Zigmund & Snaith, 1983). This questionnaire is designed as a global measure of emotional distress, evaluating mild and mixed features of mood disorders (Razavi et al., 1990; Hopwood et al., 1991; Ibbotson et al., 1994; Van't Spijker et al., 1997; Costantini et al., 1999). Subjects rate the frequency of anxious or depressive symptoms experienced over the past week. The HADS total score ranges from 0 to 42, a higher score indicating more distress. This questionnaire has been validated in French in a general medical population (Lépine, 1997) and in cancer inpatients (Razavi et al., 1989) and is widely used in the field of cancer (Hopwood et al., 1991; Ibbotson et al., 1994; Ford et al., 1995; Payne et al., 1999; Reuter & Härtner, 2001). Using the HADS as a global scale, cutoff scores for overall psychological distress (adjustment and major anxiety/depressive disorders) vary, ranging from 10/11 (to detect emotional distress/adjustment disorders and major mood disorders) to 18/19 (to detect major mood disorders) for example, cutoff score at 10 (Razavi et al., 1990; Costantini et al., 1999), 11 (Aass et al., 1997; Kugaya et al., 1998), 13 (Razavi et al., 1990; Hall et al., 1999), 14 (Ibbotson et al., 1994; Brédart et al., 1999), 15 (Roth et al., 1998; Kugaya et al., 2000), 16 (Bérard et al., 1998; Reuter & Härtner, 2001), and 19 (Razavi et al., 1990; Hopwood et al., 1991).

A cutoff point needs to be chosen in relation to the screening requirements arising from the specific clinical and economic situation (e.g., choosing a low cutoff raises sensitivity, whereas an increased number of false positives would inappropriately increase the staff work load). We chose a cutoff value greater than or equal to 15 to detect patients with a significant level of emotional distress, as well as to allow comparison with the studies using both the HADS and the DT as screening tools (Roth et al., 1998; Jacobsen et al., 2005). Our strategy was guided by the need to avoid "missing" any patient presenting a major anxiety or depressive disorder requiring specific psycho-oncological intervention. This HADS cutoff score of 15 appeared to detect significant clinical distress with an adequate level of accuracy (Jacobsen et al., 2005).

# EORTC Core Quality of Life Questionnaire

The EORTC QLQ-C30 is a quality of life scale developed by the European Organisation for Research and Treatment of Cancer and specifically designed for cancer patients (Aaronson et al., 1993). The EORTC QLQ-C30 is composed of five functional scales, three symptom scales, six single-item scales, and one global health status scale. Scale scores are calculated by averaging items within scales and transforming average scores linearly. All of the scales range in score from 0 to 100. A high score for functional or global health status scales represents a high/healthy level of functioning; a high score for a symptom scale/item indicates a high level of symptomatology or problems.

# **Statistical Analysis**

The determination of the clinically significant "distress" cutoff value was performed using the ROC method and a HADS total score of 15 or greater as a reference. Representing ROC analyses on a curve is a way of expressing the relationship between the true positive rate (sensitivity) and the false positive rate (1 - specificity) for different cutoff scores. The sensitivity of a test is its ability to detect cases, and its specificity refers to its ability to detect noncases. The curve is a representation of the ability of the screening instrument to discriminate between cases and noncases (Razavi et al., 1990). We selected the point on the ROC curve that maximized test sensitivity and specificity, so as to avoid missing cases.

Pearson's correlation coefficients were used to test the relationship between PDS and HADS total, HAD-A, or HAD-D scale scores. Nonparametric Mann– Whitney and Kruskal–Wallis tests were used to test the relationship between PDS scores and variables with two, or two or more values. Multivariate analysis was performed according to descending logistic regression methods. A significance threshold equal to 0.20 in univariate analysis was adopted for selection of variables to be included in the model.

Statistical analyses were performed using Epi-Info 6.04, S-Plus, and SAS Version 8.1 software packages.

# RESULTS

# **Demographic and Clinical Characteristics**

Of the 598 patients who were approached, 561 agreed to participate in the study (94%). No differ-

ence was noted between patients who participated and patients who refused in terms of sociodemographic characteristics (recruitment hospital, gender, age) or cancer-related characteristics (tumor site, time since last medical event [diagnosis, metastasis, recurrence], current stage, or presence of disease progression, metastasis or recurrence). Table 1 lists patient demographic and clinical characteristics. Mean (SD) age of the study sample was 57.5 (14.6) years with 84 (15%) of the patients over the age of 69 years. Three-hundred and three (54%) patients had a level of education below secondary school diploma. Disease duration and severity were heterogeneous across patients; 106 (19%) patients had metastatic cancer and 125 (22%) subjects were taking analgesics.

Mean (*SD*) and range of the HADS total, HAD-A, and HAD-D scores were respectively 13.3 (6.8) and 0-36; 8.2 (4.2) and 0-21; 5.0 (3.9) and 0-19. The number (percentage) of patients scoring 67 or less ( $\leq$ 75th percentile, meaning poorer functioning) on the EORTC QLQ-C30 physical, role, emotional, cognitive, social, and global health status scales were, respectively, 155 (28%), 184 (33%), 221 (39%), 215 (38%), 187 (33%), and 310 (55%).

One third of the study population was receiving professional psychological help (31%), including psychotherapy (2%), psychotropic drugs (21%), or a combination of the two (8%). One hundred thirty-one subjects (23%) reported a difficult professional, emotional, or financial situation and almost the same proportion (21%) reported lack of support from their friends and family.

# Relationship between the PDS, HADS, and EORTC QLQ-C30 Scores

Convergent validity of the PDS was tested by assessing the correlations between the PDS and the HADS total and subscale scores. Pearson's correlation coefficient between the PDS scale and the HADS global scale was .64 (p < .0001) and .61 between the PDS scale and HADS anxiety subscale (p < .0001). Pearson's correlation coefficient between the PDS scale and the HADS depression subscale was .39 (p < .0001).

Statistically significant correlations were observed between the PDS scores and the EORTC QLQ-C30 "emotional functioning" and "global health status" subscales, with Spearman correlation coefficients of -.56 (p < .0001) and -.44 (p < .0001), respectively.

PDS scores were also significantly related to deterioration in the EORTC QLQ-C30 physical, role, cognitive, or social functioning scores and to increasing symptom scores (p < .001 for all correlation

		Number	Rate (%)
Sociodemographic characteristics			
Hospital	Curie/IGR	335/226	60/40
Gender	Male/female	270'/291	52'/48
Age	Under 50 years	221	39
5	50–59 years	137	25
	60–69 years	119	21
	Over 69 years	84	15
Family status	Living single/with partner	165/396	29/71
Level of education	Under secondary school diploma/with higher education	303/258	54/46
Professional status	Active/retired/other <sup>a</sup>	273/250/	49/44/
		38	7
Cancer-related characteristics			
Duration of disease and severity <sup>b</sup>	Under or equal to 12 months	100	18
	More than 12 months	461	82
Metastatic cancer	Yes/no	106/455	19/81
Disease progression	Yes/no	127/434	23/77
Ongoing cancer therapy	Yes/no	323/238	58/42
Analgesic treatment	Yes/no	125/436	22/78
<b>Psychological characteristics</b>			
Psychological treatment	Yes/no	172/389	31/69
Being in a difficult situation	Yes/no	$131^{'}\!/430$	$23^{'}/77$
Presence of social support	Yes/no	441/120	$79^{\prime}/21$

Table 1. Demographic and clinical characteristics

<sup>a</sup>Homemakers, unemployed, disabled.

<sup>b</sup>Two missing data.

tests), except for the diarrhea and financial difficulty scales.

### Establishment of a Psychological Distress Scale Cutoff Score

The PDS scores did not show a normal distribution (see Figure 1). The mean PDS score on a scale from 0 to 10 was  $2.9 \pm 3.0$  with a median of 1.8. The first and third quartiles revealed scores of 0.3 and 5.3, respectively. Ninety-eight subjects (17%) reported a score of 0.

ROC analysis was used to determine whether scores on the PDS could validly distinguish whether or not a patient met criteria for clinically significant



Fig. 1. Score distribution of the Psychological Distress Scale (PDS) (n = 561).

psychological distress as measured by the HADS cutoff score of 15 (Roth et al., 1998; Jacobsen et al., 2005).

The ROC curve graphically represents the sensitivity and specificity coefficients that would be generated using each possible cutoff score in the PDS range, the accuracy of the cutoff score being determined by calculating the area under the curve (AUC). A cutoff score of 3 yielded the optimal ratio of sensitivity (.76) to specificity (.82) using the HADS cutoff score of 15 as a criterion for the presence of clinically significant distress (see Fig. 2).



**Fig. 2.** ROC curve analysis comparing the PDS scores to established HADS cutoff score; HADS cutoff value above or equal to 15.

For a cutoff value  $\geq 3$  for the PDS, we obtained a likelihood ratio for a positive test (LR<sub>P</sub>) of 4.22 and a likelihood ratio for a negative test (LR<sub>N</sub>) of 0.29. We also obtained a positive predictive value (or precision rate, i.e., proportion of patients with positive test results who are correctly diagnosed) of .69 and a negative predictive value (proportion of patients with negative test results who are correctly diagnosed) of .87, with a false-positive rate of 18% and a false-negative rate of 24% (see Table 2).

### Relationship of Psychological Distress Scale Cutoff Score to Sociodemographic, Medical and Psychosocial Characteristics

The relationship between sociodemographic variables and scores that met or did not meet the PDS cutoff score of 3 evidenced gender (women demonstrating a higher PDS score than men) as the only significantly associated variable. Age was not related to PDS scores (see Table 3).

In univariate analyses, among clinical and psychosocial variables, scores above or below the PDS cutoff score of 3 were significantly related to tumor site, analgesic use, professional psychological help, perceived psychosocial difficulties, and perceived lack of social support. The psychological distress rate was 35% (195 patients) using the HADS cutoff score of 15, and 38% (215 patients) using the PDS cutoff score of 3. This prevalence varied according to tumor sites. The highest rates of psychological distress as measured by the PDS and the HADS were observed in breast, gynecological, and brain cancer patients, and the lowest in prostate cancer patients.

A nonsignificant trend toward higher PDS scores was observed for patients with a metastatic disease compared to local/loco-regional disease and for patients with disease progression compared to those in remission. Patients receiving cancer therapy at the time of the study presented higher PDS scores than

**Table 2.** Frequency of correct and incorrect classifi-cations when using the PDS cutoff of 3, with theHADS cutoff of 15 used as a classification criterion

	DS		
HADS	<3	$\geq 3$	Total
<15 >15	$300 \\ 46$	66 149	366 (65.3%) 195 (34 7%)
Total	346 (61.7%)	215 (38.3%)	561

For a cutoff value  $\geq 3$  for the PDS, the likelihood ratio for a positive test (LR<sub>P</sub>) is 4.22 and the likelihood ratio for a negative test (LR<sub>N</sub>) is 0.29.

those not currently receiving cancer therapy (i.e., patients returning for follow-up).

With regard to psychosocial variables,  $\chi^2$  analyses were used to determine whether the scores above or below the PDS cutoff score of 3 were associated with the presence of each of the three psychosocial criteria; all were found to be very strongly correlated with psychological distress: Patients reporting financial, professional, or personal difficulties had higher scores than those not reporting such difficulties. Conversely, patients reporting support from their family and friends had lower scores.

A descending logistic regression analysis was performed, in which all order 1 interactions with tumor site were studied and including gender, level of education, professional status, tumor site, stage of disease, disease progression, ongoing cancer therapy, analgesic use, professional psychological help, perceived psychosocial difficulties, and lack of social support.

For all tumor sites, a significantly (or borderline) higher rate of distress was observed for women (p < .0007), patients presenting disease progression (p = .12), patients taking analgesics (p = .03), those receiving psychological intervention (p < .0001), those reporting psychosocial problems (p < .0001), and those perceiving a lack of social support (p < .002) (see odds ratio and confidence intervals in Table 3).

# DISCUSSION

The findings of this study indicate that the French version of the single-item Distress Thermometer, which we have called the Psychological Distress Scale, may be effective in detecting cancer patients with clinically significant distress. Using the HADS-established criterion for identifying psychological distress (score cutoff  $\geq 15$ ), a PDS cutoff score of 3 was found to possess optimal sensitivity (0.76) and specificity (0.82) to enable distinction between patients with clinically significant anxiety or depression and those without these disturbances.

This study provides additional information on the performance of a single-item psychological distress screening instrument on a culturally distinct cancer population compared to previous studies (Akizuki et al., 2003; Gil et al., 2005; Jacobsen et al., 2005; Ozalp et al., 2007).

In a clinical setting, the sensitivity of an instrument is of primary importance, as it is crucial to keep rates of false negative as low as possible (Hall et al., 1999). However, threshold values may have to be determined by resources available to the staff. In this study, the specificity level is also good, indicating that few false positives (18%) will occur,

		% of patients with a PDS score $\ge 3$	Univariate analysis: <i>p</i> value	Multivariate analysis: <i>p</i> value	Odds ratio (confidence interval)
Sociodemographic characteristics					
Hospital	Curie/IGR				
Gender	Male/female	29/47	< .0001	.0007	1.81(1.25 - 2.63)
Age	Under 50 years	40	.17		
	50–59 years	43			
	60–69 years	37			
	Over 69 years	29			
Family status	Living single/with a partner	40/38	.60		
Level of education	Under secondary school diploma/with higher education	40/36	.40		
Professional status	Active/retired/other <sup>a</sup>	41/35/39	.38		
Cancer-related characteristics					
Duration of disease and severity <sup>b</sup>	Under or equal to 12 months/more than 12 months	44/37	.20		
Metastatic cancer	Yes/no	45/38	.10	n.s.	
Disease progression	Yes/no	45'/36	.08	.12	
Ongoing cancer therapy	Yes/no	$42^{'}/36$	.12	n.s.	
Analgesic treatment	Yes/no	52/34	.0004	.03	1.65(1.07 - 2.55)
Sites	Breast	53	.0004	n.s.	
	Eye	36			
	ENT	34			
	Gynecological	50			
	Lung	30			
	Brain	46			
	Prostate	17			
	Other cancers	38			
Psychological					
Psychological	Yes/no	53/32	<.0001	<.0001	2.10(1.42 - 3.11)
Being in a difficult	Yes/no	60/32	<.0001	<.0001	$2.50\ (1.62 - 3.83)$
Presence of social support	Yes/no	33/57	<.0001	.002	1.98 (1.27-3.08)

Table	3. Relationship	of PDS cute	off score of 3	to sociodemogra	phic. medical	and psych	nosocial	variables
TUNIO					million million		vooovuuv	

<sup>a</sup>Homemakers, unemployed, disabled.

<sup>b</sup>Two missing data.

reducing the overall misclassification rate and increasing the reliability of the clinical test in detecting cases.

The PDS screening procedure appeared acceptable in this large mixed-site cancer patient sample, distributed fairly evenly in terms of age, gender, and educational level, and approached in two major cancer centers in France serving a wide range of cancer population. The screening procedure appeared acceptable with a 94% response rate. Moreover, PDS scores varied in the expected direction with psychosocial characteristics such as perceived social support and emotional, professional, or financial difficulties. Additional findings were that patients who scored at or above the PDS cutoff of 3 were more likely to be female, to be taking analgesics, to be receiving professional psychological help, and to present progression.

The cutoff score of 3 found is this study is lower than those (cutoffs of 4 or 5) found previously in mixed cancer site samples and using the HADS or BSI as comparative screening instruments (Akizuki et al., 2003; Gil et al., 2005; Jacobsen et al., 2005; Ozalp et al., 2007). With these clinical thresholds, these studies obtained DT levels of sensitivity and specificity of 84% and 61% (Akizuki et al., 2003), 77% and 68% (Jacobsen et al., 2005), and 73% and 59% (Ozalp et al., 2007).

Linguistic, cultural, and methodological factors may be suggested to explain these differences. First, the French translation of the word "distress" connotes more intense psychological suffering than in English, and this may also differ from other languages associated with the use of the distress thermometer. In addition, although there may indeed be cross-cultural differences in terms of word meaning, there may also be differences in the actual reporting of psychological distress (Jacobsen et al., 2005). Second, the adaptation of the thermometer picture to a 10-cm vertical line may affect the way in which patients respond to the instructions. Moreover, the use of different screening tools (e.g., HADS or BSI) or cutoff values (e.g., HADS  $\geq 10/11$ or 15) with which the distress thermometer was compared, may also explain the discrepancies with our results.

A higher DT cutoff score (cutoff = 4) has also been found in bone marrow transplant patients (Ransom et al., 2006), highlighting the possibility that clinical factors may also influence the choice of score thresholds. Hoffman et al. (2004) underlined the difficulty in determining a single cutoff score that could clearly maximize sensitivity and specificity across clinical conditions. The prevalence of psychological disorders varies according to patients' clinical characteristics (type of tumor, stage of disease, time since diagnosis, modes of treatment, etc.); a high prevalence would justify privileging cutoff scores associated with greater sensitivity (Razavi et al., 1992).

With this lower PDS cutoff score of 3 associated with a low false positive rate (18%), 38% patients were identified as presenting clinical psychological distress. This psychological distress rate observed in a French cancer patient population, although more elevated, compares with similar rates of emotional distress during the course of cancer in North America (Zabora, 1998; Carlson & Bultz, 2003; Hegel et al., 2006) as well as in other European countries (Brédart et al., 1999; Gil et al., 2005; Strong et al., 2007).

Large cross-sectional studies have identified that female gender, younger age, active or advanced disease, pain, and financial or material challenges were predictive of greater emotional distress (Aass et al., 1997; Brédart et al., 1999; Skarstein et al., 2000; Zabora et al., 2001; Carlson et al., 2004; Strong et al., 2007). In this study, female gender, taking analgesics, receiving psychological/psychiatric help, perceived psychosocial difficulties, lack of social support, and the various aspects of the quality of life profile were all found to be associated with psychological distress. Concerning the relationship between self-reported measures of distress and quality of life or perceived psychosocial difficulties, the crosssectional design of this study does not enable determination of causal relationships. However, it may be that the level of each outcome measure tends to be predictive of the other; physical and psychosocial problems and psychological distress appear largely interrelated. Moreover, other studies have underlined the distressing nature of many physical symptoms (Jacobsen et al., 2005); the association between PDS scores in this study and symptom scores on the EORTC QLQ-C30 may reflect this observation.

The PDS scores were more significantly associated with the HADS anxiety subscale. This compares to Gil et al. (2005) and Patrick-Miller et al. (2004), suggesting that the PDS assesses anxiety, whereas it explores depression to a lesser extent.

Patients receiving professional psychological help were those with the greatest psychological distress. Considering that among these patients, 75% were receiving psychotropic drugs, we might question the efficacy of this medical treatment to alleviate their psychological disorders; however, this relationship may also reflect a history of anxiety and depressive disorders, which is a risk factor for psychological distress (Harrison & Maguire, 1994).

After adjustment for other factors, we did not confirm any association between psychological distress and tumor site. The few studies that have compared the prevalence of psychological morbidity according to tumor site did not demonstrate any link after taking into account symptoms such as pain. Other studies are required to determine whether there are any differences related to the disease itself or whether these differences can be explained by adverse effects of treatments or physical symptoms, for example (Pinder et al., 1993).

A limitation of this study is the use of a psychometric tool (the HADS) to assess psychological morbidity and determine a PDS cutoff score on this basis, although we followed the same methodology as other investigations (Patrick-Miller et al., 2004; Gil et al., 2005; Jacobsen et al., 2005; Ransom et al., 2006; Ozalp et al., 2007). A clinical interview would have avoided the risk of patient misclassification. As reported previously, the HADS rate of false positives ranges from 15% to 20%. International psychometric and clinical data from the HADS indicate that the instrument's psychometric performance is good (Osborne et al., 2004). Besides, even clinical interviews may evidence diagnostic errors because, for example, they may lack the specific criteria to diagnose anxiety or depressive disorders in the medical patients. No interview schedule is completely reliable: for instance, a reported 61% concordance in cases of psychiatric illness between the Psychiatric Assessment Schedule and the Present State Examination (Dean et al., 1983). The aim of this study was to assess the feasibility of a psychological distress screening procedure and to provide an effective tool to detect potential cases of psychological distress to refer to the psycho-oncology service for a more detailed psychiatric assessment. We chose a HADS threshold score of 15, maximizing HADS accuracy in identifying clinical cases.

A second limitation of this study relates to the study sample characteristics, composed of relatively few metastatic patients, only cancer outpatients, and patients recruited in urban cancer centers, restricting the scope for generalizing the results.

Finally, the present study design does not inform on the efficacy of a psychological screening procedure, which is a prerequisite to early detection and referral of psychologically distressed cancer patients. To date, studies addressing the effectiveness of a psychological distress screening program have shown that, among patients receiving minimal psychosocial intervention as part of their initial cancer care, a distress screening program did not improve quality of life. Earlier, Maguire et al. (1980, 1983) had found that systematic monitoring of newly diagnosed cancer patients resulted in better recognition and appropriate psychosocial management of patients with adaptation problems. Recent metaanalyses suggest that preventative psychological interventions in cancer patients may have a moderate clinical effect upon anxiety but not on depression (Sheard & Maguire, 1999).

Further research should also address the overall psychometric performance (validity, reliability, responsiveness) of the PDS to enable this tool to be used as a clinical research instrument (De Boer et al., 2004).

# CONCLUSION

Our study has enabled us to validate the PDS, a French version of the distress thermometer developed by the NCCN (National Comprehensive Cancer Network, 2003) for detecting the presence and, subsequently, when necessary, the intensity of psychological distress in a cancer patient population. This tool can also be used to identify a number of factors (sociodemographic and cancer-related characteristics) liable to influence distress.

Improvement of the quality of care provided for cancer patients must take into account all aspects of the patient's daily life, particularly his or her psychological state. With growth of holistic patient management, psychosocial approaches will need to be developed and encouraged in cancer care centers. It is important to develop methods allowing detection of the patients with the greatest psychological difficulties, who are often neglected in daily medical practice due to a lack of time and resources, by using a simple and flexible methodology (Cull et al., 1995). As proposed by certain authors (Hopwood et al., 1991; Roth et al., 1998), a two-stage process of assessment could be used: After screening for psychological distress in all patients using simple self-administered questionnaires, patients presenting scores above the cutoff value could then be assessed further, for example, by a specialist nurse (Shimizu et al., 2005). This would provide a practical way of identifying patients in real need of specific psycho-oncological intervention.

A generalization of this method, allowing detection of anxiety and depression disorders and quality of life assessment, is acceptable for the patient and for the oncologist and could result in more effective psycho-oncological management of cancer patients.

# ACKNOWLEDGMENTS

We thank Dr. Jimmie C. Holland and Dr. Andrew Roth for their permission to use the distress thermometer and for their advice.

We thank the following departments of the Institut Curie in Paris and the Institut Gustave Roussy in Villejuif for their cooperation in this study: departments of Chemotherapy, Surgery, Gynecology, Neurology, Ophthalmology, Ear, Nose and Throat, Respiratory Medicine, Radiotherapy, and Urology. We also thank the staff of the Institut Curie in Paris and the Institut Gustave Roussy in Villejuif for their technical contributions to this study, doctors, nursing administrators, nurses, committees, and all reception personnel. We thank all staff of the Institut Curie Biostatistics Department for statistical analyses for this study. Finally, we thank all patients for their participation in this study. This research was sponsored by Programme Hospitalier de Recherche Clinique (PHRC), France.

#### REFERENCES

- Aaronson, N.K., Ahmedzai, S., Bergman, B., et al. (1993). The European Organization for Research and Treatment of Cancer QLQ-C30: A quality-of-life instrument for use in international clinical trials in oncology. *Journal of the National Cancer Institute*, 85, 365–376.
- Aass, N., Fossa, S.D., Dahl, A.A., et al. (1997). Prevalence of anxiety and depression in cancer patients seen at the Norwegian Radium Hospital. *European Journal of Cancer*, 33, 1597–1604.

- Akizuki, N., Akechi, T., Nakanishi, T., et al. (2003). Development of a brief screening interview for adjustment disorders and major depression in patients with cancer. *Cancer*, 97, 2605–2613.
- Bérard, R.M.F., Boermeester, F., & Viljoen, G. (1998). Depressive disorders in an out-patient oncology setting: Prevalence, assessment, and management. *Psycho-Oncology*, 7, 112-120.
- Brédart, A., Didier, F., Robertson, C., et al. (1999). Psychological distress in cancer patients attending the European Institute of Oncology in Milan. Oncology, 57, 297–302.
- Bultz, B.D. & Carlson, L.E. (2006). Emotional distress: The sixth vital sign—Future directions in cancer care. *Psycho-oncology*, 15, 93–95.
- Carlson, L.E. & Bultz, B.D. (2003). Cancer distress screening. Needs, models, and methods. *Journal of Psychosomatic Research*, 55, 403–409.
- Carlson, L.E., Angen, M., Cullum, J., et al. (2004). High levels of untreated distress and fatigue in cancer patients. *British Journal of Cancer*, 90, 2297–2304.
- Costantini, M., Musso, M., Viterbori, P., et al. (1999). Detecting psychological distress in cancer patients: Validity of the Italian version of the Hospital Anxiety and Depression Scale. Supportive Care in Cancer, 7, 121-127.
- Cull, A., Stewart, M., & Altman, D.G. (1995). Assessment of and intervention for psychosocial problems in routine oncology practice. *British Journal of Cancer*, 72, 229–235.
- De Boer, A.G.E.M., van Lanschot, J.J.B., Stalmeier, P.F.M., et al. (2004). Is a single-item visual analogue scale as valid, reliable and responsive as multi-item scales in measuring quality of life? *Quality of Life Research*, 13, 311–320.
- Dean, C., Surtees, P.G., & Sashidharan, S.P. (1983). Comparison of research diagnostic systems in an Edinburgh community sample. *British Journal of Psychiatry*, 142, 247–256.
- Derogatis, L.R. (2000). Brief Symptom Inventory-18. Minneapolis MN: National Computer Systems, Inc.
- Derogatis, L.R., Morrow, G.R., Fetting, J., et al. (1983). The prevalence of psychiatric disorders among cancer patients. *Journal of the American Medical Association*, 249, 751–757.
- Fallowfield, L., Ratcliffe, D., Jenkins, V., et al. (2001). Psychiatric morbidity and its recognition by doctors in patients with cancer. *British Journal of Cancer*, 84, 1011–1015.
- Ford, S., Lewis, S., & Fallowfield, L. (1995). Psychological morbidity in newly referred patients with cancer. *Jour*nal of Psychosomatic Research, 39, 193–202.
- Gil, F., Grassi, L., Travado, L., et al. (2005). Use of distress and depression thermometers to measure psychosocial morbidity among southern European cancer patients. *Supportive Care in Cancer*, 13, 600–606.
- Goldberg, D. (1978). Manual of the General Hospital Questionnaire. Windsor, UK: NFER Publishing.
- Hall, A., A'Hern, R., & Fallowfield, L. (1999). Are we using appropriate self-report questionnaires for detecting anxiety and depression in women with early breast cancer? *European Journal of Cancer*, 35, 79–85.
- Harrison, J. & Maguire, P. (1994). Predictors of psychiatric morbidity in cancer patients. British Journal of Psychiatry, 165, 593-598.
- Hegel, M.T., Moore, C.P., Collins, E.D., et al. (2006). Distress, psychiatric syndromes, and impairment of

function in women with newly diagnosed breast cancer. *Cancer*, 107, 2924–2931.

- Hoffman, B.M., Zevon, M.A., D'Arrigo, M.C., et al. (2004). Screening for distress in cancer patients: The NCCN rapid-screening measure. *Psycho-oncology*, 13, 792–799.
- Holland, J.C. (1997). Preliminary guidelines for the treatment of distress. Oncology, 11, 109-117.
- Holland, J.C., Andersen, B., Breitbart, W.S., et al. (2007). Distress management. Journal of the National Comprehensive Cancer Network, 5, 66–98.
- Hopwood, P.H., Howell, A., & Maguire, P. (1991). Screening for psychiatric morbidity in patients with advanced breast cancer: Validation of two self-report questionnaires. *British Journal of Cancer*, 64, 353–356.
- Ibbotson, T., Maguire, P., Selby, P., et al. (1994). Screening for anxiety and depression in cancer patients: The effects of disease and treatment. *European Journal of Cancer*, 30A, 37–40.
- Jacobsen, P.B., Donovan, K.A., Trask, P.C., et al. (2005). Screnning for psychologic distress in ambulatory cancer patients. *Cancer*, 103, 1494–1502.
- Keller, M., Sommerfeldt, S., Fischer, C., et al. (2004). Recognition of distress and psychiatric morbidity in cancer patients: A multi-method approach. *Annals of Oncology*, 15, 1243–1249.
- Kugaya, A., Akechi, T., Okuyuma, T., et al. (1998). Screening for psychological distress in Japanese cancer patients. *Japanese Journal of Clinical Oncology*, 28, 333–338.
- Kugaya, A., Akechi, T., Okuyama, T., et al. (2000). Prevalence, predictive factors, and screening for psychologic distress in patients with newly diagnosed nead and neck cancer. *Cancer*, 88, 2817–2823.
- Lépine, J.P. (1997). L'échelle HAD (Hospital Anxiety and Depression Scale). In L'évaluation Psychiatrique Standardisée en Psychiatrie, Guelfi J.D. (ed.), Fabre: tome 1.
- Maguire, P. (2002). Improving the recognition of concerns and affective disorders in cancer patients. *Annals of Oncology*, *13*(Suppl. 4), 177–181.
- Maguire, P., Brooke, M., Tait, A., et al. (1983). The effect of counselling on physical disability and social recovery after mastectomy. *Clinical Oncology*, 9, 319–324.
- Maguire, P., Tait, A., Brooke, M., et al. (1980). Effect of counselling on the psychiatric morbidity associated with mastectomy. *British Medical Journal*, 281, 1454–1456.
- National Comprehensive Cancer Network. (2003). Distress management clinical practice guidelines. Journal of the National Comprehensive Cancer Network, 1, 344–374.
- Osborne, R.H., Elsworth, G.R., Sprangers, M.A., et al. (2004). The value of the Hospital Anxiety and Depression Scale (HADS) for comparing women with early onset breast cancer with population-based reference women. *Quality of Life Research*, 13, 191–206.
- Ozalp, E., Cankurtaran, E.S., Soygür, H., et al. (2007). Screening for psychological distress in Turkish cancer patients. *Psycho-oncology*, *16*, 304–311.
- Passik, S.D., Dugan, W., McDonald, M.V., et al. (1998). Oncologists' recognition of depression in their patients with cancer. *Journal of Clinical Oncology*, 16, 1594–1600.
- Patrick-Miller, L.J., Broccoli, T.L., Levine, E., et al. (2004). Screening for psychological distress among ambulatory oncology patients: Evaluation of the distress thermometer. *Psycho-oncology*, 13, S64–S65.
- Payne, D.K., Hoffman, R.G., Theodoulou, M., et al. (1999). Screening for anxiety and depression in women with

breast cancer: Psychiatry and medical oncology gear up for managed care. *Psychosomatics*, 40, 64–69.

- Pinder, K.L., Ramirez, A.J., Black, M.E., et al. (1993). Psychiatric disorders in patients with advanced breast cancer: Prevalence and associated factors. *European Journal of Cancer*, 29A, 524–527.
- Ransom, S., Jacobsen, P.B., & Booth-Jones, M.V. (2006). Validation of the distress thermometer with bone marrow transplant patients. *Psycho-Oncology*, 15, 604–612.
- Razavi, D., Delvaux, N., Brédart, A., et al. (1992). Screening for psychiatric disorders in a lymphoma out-patient population. *European Journal of Cancer*, 28A, 1869–1872.
- Razavi, D., Delvaux, N., Farvacques, C., et al. (1989). Validation de la version française du HAD dans une population de patients cancéreux hospitalisés. *Revue de Psychologie Appliquée*, 39, 295–308.
- Razavi, D., Delvaux, N., Farvacques, C., et al. (1990). Screening for adjustment disorders and major depressive disorders in cancer inpatients. *British Journal of Psychiatry*, 156, 79-83.
- Reuter, K. & Härtner, M. (2001). Screening for mental disorders in cancer patients—Discriminant validity of HADS and GHQ-12 assessed by standardized clinical interview. *International Journal of Methods in Psychiatric Research*, 10, 86–96.
- Roth, A.J., Kornblith, A.B., Batel-Copel, L., et al. (1998). Rapid screening for psychologic distress in men with prostate carcinoma. *Cancer*, 82, 1904–1908.
- Sheard, T. & Maguire, P. (1999). The effect of psychological interventions on anxiety and depression in cancer patients: Results of two meta-analyses. *British Journal* of Cancer, 80, 1770–1780.
- Shimizu, K., Akechi, T., Okamura, M., et al. (2005). Usefulness of the Nurse-Assisted Screening and Psychiatric Referral Program. *Cancer*, 103, 1949–1956.

- Skarstein, J., Aass, N., Fossa, S.D., et al. (2000). Anxiety and depression in cancer patients: Relation between the Hospital Anxiety and Depression Scale and the European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire. *Journal of Psychosomatic Research*, 49, 27–34.
- Söllner, W., DeVries, A., Steixner, E., et al. (2001). How successful are oncologists in identifying patient distress, perceived social support, and need for psychosocial counselling? *British Journal of Cancer*, 84, 179–185.
- Söllner, W., Maislinger, S., Konig, A., et al. (2004). Providing psychosocial support for breast cancer patients based on screening for distress within a consultation-liaison service. *Psycho-oncology*, 13, 893–897.
- Strong, V., Waters, R., Hibberd, C., et al. (2007). Emotional distress in cancer patients: The Edinburgh Cancer Centre symptom study. *British Journal of Cancer*, 96, 868-874.
- Trask, P.C., Paterson, A., Riba, M., et al. (2002). Assessment of psychological distress in prospective bone marrow transplant patients. *Bone Marrow Transplant*, 29, 917–925.
- Van't Spijker, A., Trijsburg, R.W., & Duivenvoorden, H.J. (1997). Psychological sequelae of cancer diagnosis: A meta-analytical review of 58 studies after 1980. *Psychosomatic Medicine*, 59, 280–293.
- Zabora, J.R. (1998). Screening procedures for psychological distress. In *Handbook of Psycho-Oncology*, 2nd ed., Rowland, J. & Holland J.C. (ed.), pp. 654–661. New York: Oxford University Press.
- Zabora, J., Brintzenhofeszoc, K., Curbow, B., et al. (2001). The prevalence of psychological distress by cancer site. *Psycho-oncology*, 10, 19–28.
- Zigmund, S.A. & Snaith, R.P. (1983). The Hospital Anxiety and Depression Scale. Acta Psychiatrica Scandinavica, 67, 361–370.