Use of the Distress Thermometer in Cancer Survivors: Convergent Validity and Diagnostic Accuracy in a Spanish Sample

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OBJECTIVES: To explore the performance of the National Comprehensive Cancer Network Distress Thermometer (DT) as a distress screening tool in cancer survivors.

SAMPLE & SETTING: 236 Spanish adult-onset cancer survivors who visited the Fundación Instituto Valenciano de Oncología in Valencia, Spain, for follow-up appointments.

METHODS & VARIABLES: Survivors completed the DT and the Brief Symptom Inventory 18 (BSI-18), which has established a cutoff score for identifying clinically significant distress.

RESULTS: Receiver operating characteristic curve analysis of the DT scores relative to the BSI-18 cutoff score showed good overall accuracy. For a score of 5 or greater, sensitivity, specificity, positive predictive value, negative predictive value, and clinical utility indexes indicated that the DT appeared to be satisfactory for screening but had restricted use for case finding.

IMPLICATIONS FOR NURSING: Screening for and responding to distress is considered an important part of nursing practice. The DT is suitable for use as a first-stage, quick-detection instrument in a two-step screening process to rule out noncases among Spanish post-treatment cancer survivors.

KEYWORDS cancer survivors; Distress Thermometer; psychosocial distress; diagnostic accuracy
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People who have survived cancer frequently experience long-term and late physical effects, such as pain and fatigue (Bower, 2007; Pachman, Barton, Swetz, & Loprinzi, 2012), as well as psychosocial and practical difficulties, such as fear of recurrence and issues surrounding employment, finances, and health and life insurance (Aaronson et al., 2014; de Boer, Taskila, Ojajärvi, van Dijk, & Verbeek, 2009; Duijts et al., 2014; Hoffman, McCarthy, Recklitis, & Ng, 2009; Stanton, 2012). Because of these challenges, cancer survivors are at increased risk for psychosocial distress, even many years after the completion of therapy, although definitive data regarding the prevalence of significant distress are lacking (the reported prevalence ranges from 5% to 43%) (Jefford et al., 2017; Kaiser, Hartoonian, & Owen, 2010; Mitchell, Ferguson, Gill, Paul, & Symonds, 2013; Ploos van Amstel et al., 2013; Wells et al., 2015). Psychosocial distress in cancer is defined by the National Comprehensive Cancer Network ([NCCN], 2017a) as follows:

> A multi-determined unpleasant emotional experience of a psychological, social, spiritual and/or physical nature that may interfere with the ability to cope effectively with cancer, its physical symptoms and its treatment. Distress extends along a continuum, ranging from common normal feelings of vulnerability, sadness, and fears to problems that can become disabling, such as depression, anxiety, panic, social isolation, and existential and spiritual crisis. (p. MS-4)

In the early 2000s, distress was recognized as the sixth vital sign in cancer care (Bultz & Carlson, 2005); consequently, guidelines of a number of international professional societies and regulatory organizations (e.g., CanCon in Europe and NCCN in the United States) recommended integration of screening for

distress as a regular step in the long-term follow-up care of people who have survived cancer (Albreht, Kiasuwa, & Van den Bulcke, 2017; NCCN, 2017b). Physical and psychological effects present challenges for healthcare systems, which have to guarantee appropriate follow-up care and quality of life, moving from how long people live after a diagnosis to how well people can expect to live from diagnosis onward (Albreht et al., 2017).

The recommendation for the routine use of screening for distress after active treatment may benefit from the availability of an ultrashort instrument, such as the NCCN Distress Thermometer (DT). The DT, developed by Roth et al. (1998), is a single-item self-report method for identifying psychological distress ranging from 0 (no distress) to 10 (extreme distress). Since its introduction, the DT has been widely recommended for screening distress in people with cancer (NCCN, 2017a; Ma et al., 2014). Its potential advantages versus other distress screening tools are its brevity, ease of administration and scoring, and acceptability to healthcare providers and patients. In addition, many studies carried out in different countries and cultures have endorsed the usefulness and adequate accuracy of the DT to correctly identify clinically significant distress (a highly severe and impairing psychological response that requires professional support), despite some shortcomings—in particular, the lack of specificity of the DT to rule out false-positive cases and mixed findings regarding the optimal cutoff score (Donovan, Grassi, McGinty, & Jacobsen, 2014; Ma et al., 2014; Snowden et al., 2011). However, research on the use of the DT in the post-treatment survivor group is inconclusive. Studies in adult-onset cancer survivors are scarce, and the results are mixed. Most studies compare the performance of the DT with that of other longer instruments, like the Hospital Anxiety and Depression Scale (Boyes, D'Este, Carey, Lecathelinais, & Girgis, 2013; Roerink et al., 2013), the Brief Symptom Inventory 18 (BSI-18) (Merport, Bober, Grose, & Recklitis, 2012), the University of Washington Quality of Life scale (Ghazali et al., 2017), and even the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders (4th ed., depressive and anxiety disorder modules) (Recklitis, Blackmon, & Chang, 2016). The findings show that the accuracy of the DT to detect clinically significant distress in adult post-treatment survivors is not always satisfactory. The DT has shown higher values of sensitivity than specificity in some cases (72–93 versus 40–42) (Hong & Tian, 2013; Olesen et al., 2018) but higher values of specificity than sensitivity in others (52–60 versus 86–90) (Craike, Livingston, & Warne, 2011; Merport et al., 2012). In addition, there is a lack of consensus about the DT's optimal cutoff score for clinically relevant distress; scores based on receiver operating characteristic curve analyses range from 2 to 5 across different studies and even in relation to the assessment's proposed objective (Boyes et al., 2013). Therefore, more studies are needed to evaluate the performance of the DT (Ma et al., 2014) in post-treatment survival.

In the Spanish context, the DT has been validated in people with heterogeneous cancer in terms of the phase of care (Gil, Grassi, Travado, Tomamichel, & González, 2005; Martínez, Andreu, Galdón, & Ibáñez, 2015; Martínez, Galdón, Andreu, & Ibáñez, 2013) but not specifically in post-treatment survivors. However, this stage of cancer trajectory validation is important; a review by Donovan et al. (2014) showed that cutoff scores for clinically relevant distress vary according to the characteristics of the patients being screened and the setting. Therefore, the aim of the current study was to examine the accuracy of the DT to detect clinically significant distress as assessed by the BSI-18 (criterion measure) in Spanish post-treatment survivors of adult-onset cancer.

Methods

Participants and Procedure

A convenience sample of 254 participants who visited the Fundación Instituto Valenciano de Oncología in Valencia, Spain, for follow-up medical appointments were approached. The study was approved by the institutional ethics committee. To be eligible, the following was required of participants:

- Aged 18 years or older
- Diagnosed with cancer and without any symptoms or signs of cancer at the time
- Finished surgery, chemotherapy, or radiation therapy treatments at least four weeks before the study
- Had knowledge of the Spanish language

Participants received information about the study, and 236 (93%) gave informed consent and completed the questionnaire package.

Measures

Sociodemographic and medical data: A self-report form developed for this study collected age, marital status, education level, and employment status. Cancer-related details (cancer type and time elapsed since the end of primary treatment) were gathered using a chart review.

Distress Thermometer: The DT is a one-item visual analog scale that measures psychological distress (Roth et al., 1998). Individuals indicate on an 11-point scale (with 0 indicating no distress and 10 indicating extreme distress) how distressed they felt in the previous seven days.

This study used the Spanish version of the DT, which has shown satisfactory diagnostic accuracy (area under the curve [AUC] = 0.82 or greater, sensitivity = 90% or greater, specificity = 64% or greater, predictive positive value [PPV] = 25% or greater, and negative predictive value [NPV] = 97% or greater for a selected DT cutoff of 5) (Martínez et al., 2013, 2015).

Brief Symptom Inventory 18: The BSI-18 (Derogatis, 2013) is a self-report symptom checklist comprising 18 items rated on a five-point Likert-type scale. Respondents are asked to rate each item according to how they have been feeling during the past seven days. The scale provides an overall measure of psychological distress (Global Severity Index [GSI]) and three symptom scores (somatization, depression, and anxiety). In accordance with Derogatis (2001), scores are transformed into t scores to identify clinically significant distress using gender-specific normative data (t scores of 63 or greater on the GSI or on at least two subscales are classified as "caseness"). The BSI-18 has been used as a criterion scale for the DT (Bevans et al., 2011; Hoffman, Zevon, D'Arrigo, & Cecchini, 2004; Jacobsen et al., 2005; Merport et al., 2012) and has shown satisfactory psychometric properties in studies of a Spanish population of people with cancer (Galdón et al., 2008; Martínez, Conchado, Andreu, & Galdón, 2019). In those studies, the confirmatory factor analyses supported the good structural validity of the instrument, and Cronbach alpha values ranged from 0.91 to 0.81 for GSI and from 0.84 to 0.62 for subscales. In addition, composite reliability values obtained in the second study ranged from 0.9 to 0.69. Regardless of the index used, the lowest values in reliability were obtained by the somatization subscale. For the current study, the GSI and subscales showed adequate reliability (Cronbach α_{GSI} = 0.92, Cronbach $\alpha_{somatization}$ = 0.73, Cronbach $\alpha_{depression}$ = 0.86, Cronbach $\alpha_{anxiety}$ = 0.86).

TABLE 1. Sample Characteristics (N = 236)

Characteristic	n	%
Sex		
Female	154	65
Male	82	35
Living situation		
Married or living with partner	162	69
Single, divorced, or widowed	74	31
Education level		
No education	28	12
Primary education	117	50
Secondary education or university	91	39
Employment status		
Retired or on sick leave	102	43
Working outside the home	63	27
Housewife	44	19
Unemployed	27	11
Cancer type		
Gynecologic	85	36
Prostate	42	18
Breast	37	16
Melanoma	30	13
Head and neck	15	6
Urinary	11	5
Other	16	7
Time in follow-up (N = 220)		
1 year or less	53	24
More than 1 year, less than 5 years	94	43
5 years or more	73	33

Note. Because of rounding, percentages may not total 100.

Data Analysis

Statistical analysis was performed using IBM SPSS Statistics, version 22.0. Descriptive statistics were used to summarize sociodemographic, medical, and psychological data. Correlations between the DT and BSI-18 (GSI and subscales) were calculated using nonparametric Spearman's rho (advised for data that do not meet the assumption of normality) to explore the convergent validity of the DT with the BSI-18. The following indices were used to study the accuracy of the DT and determine its optimal cutoff point for clinically significant distress (Doménech, 2004; Franco & Vivo, 2007):

- Global measures (AUC, fraction correct)
- Occurrence measures (sensitivity, specificity)
- Discrimination measures (PPV, NPV)

Occurrence and discrimination measures were used to calculate clinical utility indexes (UIs). The positive UI ([UI+] = sensitivity × PPV) provides rule-in accuracy (case finding), and the negative UI ([UI–] = specificity × NPV) shows rule-out accuracy (screening) (Mitchell, 2011). The statistical significance level for analyses was $p \leq 0.05$.

Results

Sample Characteristics

Sociodemographic and medical data for the 236 participants are shown in Table 1. The mean age was 58 years (SD = 13.4); 65% were women. More than two-thirds of the participants were living with a partner (69%), most had completed primary education (89%), 43% were retired or on sick leave, and 11% were unemployed.

The most frequent cancer type was gynecologic cancer (36%), followed by prostate cancer (18%), breast cancer (16%), and melanoma (13%). Almost one in four participants (24%) had completed their primary treatment no more than a year before, 43% had exceeded a year but had not yet reached five years post-treatment, and 33% had reached five or more years post-treatment.

Brief Symptom Inventory 18 and Distress Thermometer Scores

The mean GSI score was 10.45 (SD = 11.37, range = 0–55), and 16% of participants (37 of 236) met the criteria for caseness of distress. The mean DT score was 4.21 (SD = 3.1, range = 0–10); in accordance with the proposal of distress ranges of Hoffman et al. (2004), 66 participants (28%) reported high levels of distress (DT score of 7 or greater), 70 (30%) reported moderate levels (score of 4 to 6), and 100 (43%) reported low levels (DT score of 3 or less). Figure 1 shows the distribution of negative and positive cases of distress (as measured by the BSI-18) across the DT score range. Two of the 37 positive cases showed low DT scores, 13 had moderate scores, and 22 presented high levels of distress on the DT; 90 of the 191 negative cases had low DT scores, 61 reported moderate scores, and 40 had high DT scores.

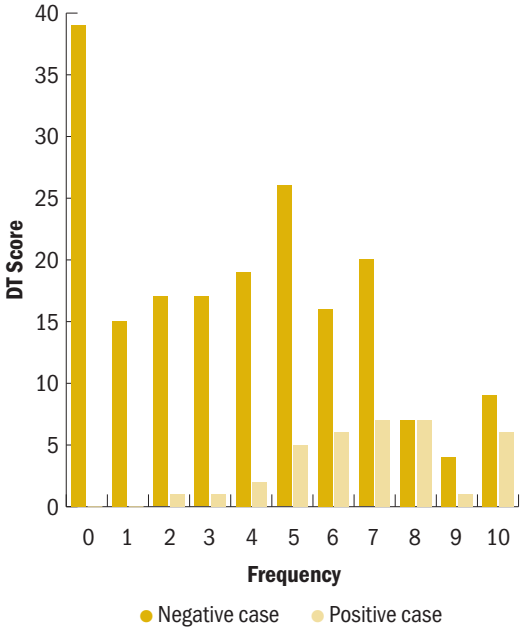
Accuracy and Convergent Validity of the Distress Thermometer

The AUC was 0.81 (95% confidence interval [0.74, 0.87]), indicating that the DT showed adequate overall accuracy in detecting distress and non-distress cases relative to the BSI-18. A graphic representation of the tradeoff between sensitivity and 1–specificity is shown in Figure 2. To evaluate the optimal cutoff point, several measures of accuracy were calculated for each DT score (see Table 2).

Taking into account these indicators, and considering screening purposes, a higher sensitivity is of greater value than a higher specificity (Olesen et al., 2018; Vodermaier & Millman, 2011). A score of 5 was considered the optimal cutoff point. The fraction correct for this score showed that 64% of patients would have been given the correct diagnosis of negative or positive. A DT cutoff of 5 allowed the detection of 33 of 37 cases of distress (sensitivity = 89%) and excluded 117 of 199 non-cases (specificity = 59%). The PPV was 29%, and the NPV was 97%. The clinical UIs showed that the rule-out accuracy of the DT was adequate (UI– = 0.57), but its rule-in accuracy was poor (UI+ = 0.26).

DT scores were significantly associated with GSI scores ($r = 0.67$, $p < 0.001$) and with each of the BSI-18 subscales (somatization [$r = 0.42$, $p < 0.001$], depression [$r = 0.56$, $p < 0.001$], and anxiety [$r = 0.62$, $p < 0.001$]).

FIGURE 1. Distribution of Positive and Negative Cases of Distress on the BSI-18 by DT Scores (N = 236)



BSI-18—Brief Symptom Inventory 18; DT—Distress Thermometer

Discussion

The main objective of this study was to examine the performance of the DT as a screening tool in Spanish post-treatment survivors of adult-onset cancer. The findings were similar to those found in previous studies of Spanish people with cancer (Andreu, Galdón, Martínez, & Martínez, 2015; Martínez et al., 2013, 2015) and indicated the adequate global accuracy of the DT scores relative to the BSI-18 cutoff score gold standard (AUC = 0.81). The DT also showed

satisfactory convergent validity; it was significantly associated with each of the BSI-18 subscales (anxiety, depression, and somatization) and with its global score (GSI).

To select the optimal cutoff point of the DT for clinically significant distress (psychological problems of all types with high levels of severity and impairment that require professional support), the authors considered a combined criterion: an optimal sensitivity (to ensure that possible cases of psychological morbidity were not missed) together with clinical UIs that combine occurrence and discrimination measures. This could potentially lead to overdetection of cases and unnecessary further evaluation. In effect, it would increase the social and personal costs associated with false positives. However, it could be argued that overdetection is preferable to underdetection in the survivorship context because of intermittent contact with healthcare providers and fewer opportunities to identify psychological distress (Boyes et al., 2013).

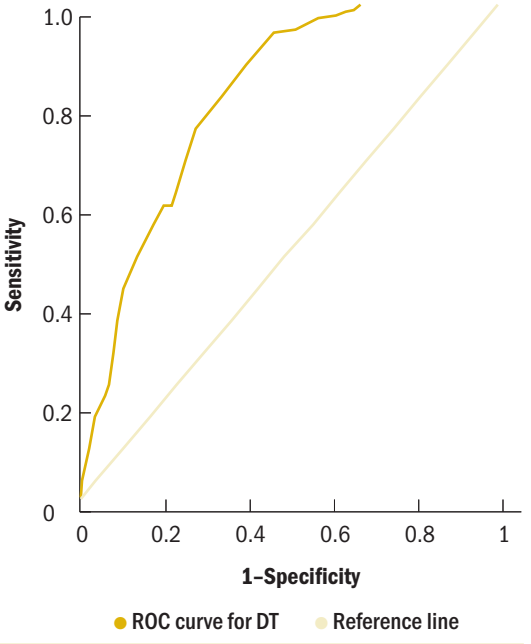
Based on these considerations, a DT cutoff score of 5 was selected to detect clinically significant distress, which was the same as the cutoff in previous studies of the Spanish cancer population. This DT cutoff point yielded a true negative in 97 of 100 negative tests (NPV) while being really negative (according to the BSI-18) in only 59% of cases (specificity); in addition, this threshold yielded a true positive in 29 of 100 positive tests (PPV) while being really positive (according to the BSI-18) in 89% of cases (sensitivity).

These data are consistent with data from studies of people who have survived cancer in which the DT showed higher levels of sensitivity than specificity (Boyes et al., 2013; Ghazali et al., 2017; Hong & Tian, 2013; Olesen et al., 2018). The results suggest that the DT is more adequate for routine screening (UI– = 0.57) (to rule out non-cases with minimal false negatives) than for case finding (UI+ = 0.26) because of its substantial number of false positives.

In terms of cancer trajectory stages, the performance of the DT at the post-treatment survivorship stage is more limited than that obtained at the active treatment stage (Ma et al., 2014). Therefore, some consensus exists that the DT cannot be used as a single screening tool for clinically significant distress (Craike et al., 2011; Hong & Tian, 2013; Merport et al., 2012; Recklitis et al., 2016). Some appropriate strategies that have been suggested to improve its accuracy for people with cancer (Martínez et al., 2013) could also be used in the stage of survivorship. For example, Craike et al. (2011) compared the overall accuracy of the DT to its combined use with the Impact Thermometer (IT) (Akizuki, Yamawaki, Akechi, Nakano, & Uchitomi, 2005). However, the combination of the DT and the IT did not improve its performance.

Some advantages of the DT are its ease of application and its effectiveness as a tool to discard cases of clinically significant distress. The DT could be used as part of a two-stage screening process, in which it serves as a first step to identify non-cases. This would require a low DT cutoff point that permits a high sensitivity and the addition of a second screening tool with more items to reduce false positives (Boyes et al., 2013; Chambers, Zajdlewicz, Youlden, Holland, & Dunn, 2014; Recklitis et al., 2016). This is the only use of the DT in the cancer survival phase that is currently supported by the NCCN (2017b).

FIGURE 2. ROC Curve for DT Scores Against BSI-18 Cutoff Scores



BSI-18—Brief Symptom Inventory 18; DT—Distress Thermometer; ROC—receiver operating characteristic
Note. The reference line corresponds to a random declassifier (i.e., it corresponds to the minimum accuracy of the classifier).

Limitations

This study has several limitations. A relatively small number of cancer survivors were recognized as clinically distressed; however, results were calculated using common standard measures, some of which

did not consider the prevalence of the event (Franco & Vivo, 2007). In addition, the data of the diagnostic accuracy of the DT were improved by using other parameters like the clinical UIs. The mixed characteristics of the sample in relation to sociodemographic and medical variables may facilitate the generalization of the results to the population of people who have survived cancer. However, the small size of the subgroups precluded an exploration of the performance of the DT as a distress screening tool taking into account relevant variables such as type of cancer and time elapsed since the end of treatment; this would have provided useful additional information about the performance of the DT. Finally, the use of a structured diagnostic interview, considered the gold standard, would have been desirable to assess psychological distress. However, it should be noted that a meta-analysis showed that the self-reported prevalence of any emotional complication was similar to the prevalence obtained using interviews (Mitchell et al., 2011).

Implications for Nursing

Screening for and responding to distress is considered an important part of nursing practice as part of a therapeutic person-centered care approach (McCormack & McCance, 2006). The success of any screening program for distress requires nursing staff to embrace distress as a nurse-sensitive outcome and acquire the confidence to provide effective psychosocial care and evidence-based symptom management (Fitch, Howell, McLeod, & Green, 2012). As indicated by Vodermaier, Linden, and Siu (2009), healthcare providers' infrequent use of high-quality screening instruments in cancer care settings may partially be because of their time constraints and insufficient knowledge about appropriate screening tools. For this reason, it is essential to provide nursing education about the routine use of screening instruments and the conceptual frameworks that guide the assessment process and score responses (Grassi, Nanni, & Caruso, 2010). Given its brevity and ease of administration, the DT should form part of a programmatic approach to detect distress. It could be used as a first mechanism in triage by ruling out a large subgroup of people who do not require future exploration of their distress levels.

KNOWLEDGE TRANSLATION

- The high sensitivity of the Distress Thermometer (DT) makes it an adequate first-stage screening instrument to assess cancer survivors' emotional distress.
- A DT score of 5 is the optimal cutoff point for clinically significant distress that correctly categorizes about 60% of the population (noncases and cases of distress).
- The use of a second instrument with the DT could increase its specificity and, consequently, improve its diagnostic accuracy in a second phase of the distress screening process.

TABLE 2. Measures of Accuracy for Each Distress Thermometer Cutoff Score

Score	Sensitivity	Specificity	PPV	NPV	UI+	UI–
1	1	0.24	0.2	1	0.2	0.24
2	1	0.31	0.21	1	0.21	0.31
3	0.97	0.43	0.24	0.99	0.23	0.43
4	0.95	0.53	0.27	0.98	0.26	0.52
5	0.89	0.59	0.29	0.97	0.26	0.57
6	0.76	0.72	0.33	0.94	0.25	0.68
7	0.59	0.8	0.35	0.91	0.21	0.73
8	0.41	0.9	0.43	0.89	0.18	0.8
9	0.22	0.93	0.38	0.86	0.08	0.8
10	0.19	0.95	0.44	0.86	0.08	0.82

NPV—negative predictive value; PPV—positive predictive value; UI—utility index

Conclusion

The DT could be used to screen for distress in the cancer post-treatment survival phase as a first step to rule out non-cases. However, it is essential to include another screening instrument with a higher level of specificity to reevaluate previously identified cases. This second step in the screening process is necessary to avoid overloading scarce available health resources.

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