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# The efficiency of distress thermometer in the determination of supporting needs for cancer inpatients

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## ABSTRACT

Psychological distress scale is highly recommended for cancer patients' care. Several psychological scales have been implemented in cancer outpatient clinics. However, the use of the psychological distress scale, particularly distress thermometer (DT), in the inpatient has not been reported. In this study, we report the efficacy of DT in the determination of cancer inpatients' supporting needs.

A total of 170 inpatients diagnosed with cancer have been enrolled in this study. Only 132 patients matched the inclusion criteria, while other cases were excluded because of other diseases associated with cancer. The standardized problem list (PL) and Hospital Anxiety and Depression Scale (HADS) were implemented in comparison with DT. Then, the cut-off score of DT was performed to identify clinically significant differences.

The analysis of the receiver operating characteristic (ROC) curve revealed that a DT cut-off score of 4 displayed 0.76 under the ROC curve. Sensitivity showed 0.86 sensitivity for cut-off score 4 and a specificity of 0.56 relative to the HADS cut-off score ( $\geq 15$ ). DT scores were found independent of medical variables such as cancer type and stage, recurrence, or metastasis. Clinical ECOG-SP showed a significant association with the DT cut-off score ( $P \leq 0.05$ ). Regarding PL, patients with scores above DT cut-off were suffering 21 of 40 problems in all categories. Furthermore, patients that scored above the DT cut-off significantly showed an association with high support needs.

DT scale showed significant performance in the evaluation of psychological distress among cancer inpatients through the efficient determination of their support needs.

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## KEYWORDS

Distress thermometer; cancer inpatients; ECOG-SP scale; cut-off score

## 1. Introduction


Distress thermometer (DT) is a newly emerged scale for screening psychological distress in patients with cancer [1,2]. Recently, a comprehensive cancer network (NCCN) strongly recommended routine screening of psychological distress for all patients with cancer [3–5]. Psychological distress could range from common normal feelings (sadness and fear) to disabling problems, such as social isolation, depression, panic, anxiety, and spiritual and existential crisis [6]. Several previous reports concluded that cancer patients have displayed considerable distress due to cancer diagnosis and its therapy [7,8]. Furthermore, psychological distress can increase the unfavourable impact on cancer patients and their quality of life [9]. It impacts the positive response to treatment [10], performance status (PS) [11], medical care satisfaction

and interactions [12], as well as survival [13]. Furthermore, unrecognized distress among cancer patients is expected to develop severe depression without appropriate therapeutic intervention, which may cause a relapse in the patient's psychological status and a failure in the appropriate response to cancer therapy. Hence, early psychosocial check and simple screening procedures could efficiently contribute to improving therapy outcomes among cancer patients [14–16].

DT scale can provide a quick and easy way to properly evaluate psychological distress among cancer patients. A previous study revealed that the implementation of DT with a cut-off score of 4 in Chinese cancer patients showed an acceptable overall accuracy and reliability [17]. Another study in Taiwan reported that a DT score of 4 was the optimal cut-off, with sensitivity and specificity of 98 and 73%,

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respectively among outpatients with cancer [18]. A recent study used DT with cut-off score 4 reported that 179 patients of 810 participants (22.1%) were suffering psychological distress and a refusal of receiving chemotherapy among younger age patients were significantly related to psychological distress [7]. However, previous studies measured and implemented DT cut-off score among cancer outpatients only but the measurement of DT cut-off score and implementation among cancer inpatients remain to be studied. Thus, we hypothesized that a determination of DT cut-off score among cancer inpatients could efficiently contribute to determine cancer inpatients psychological distress and the supportive care needs precisely. Therefore, this study aims to determine DT cut-off score among cancer inpatients and explore a clinical significance. The DT screening was performed in comparison to common distress scales in the outpatient clinics. Our results showed an efficacy of DT to determine psychological distress among cancer inpatients and explored their supportive needs.

## 2. Methodology

### 2.1. Ethical approval statement

This study has been performed according to the National Ethical Guidelines for Health and Health-related Research in China; the study was approved by the Medical Ethics Committee of our Hospital under the number 20,201,014–40.

### 2.2. Participants

Study participants were selected from the inpatient department of our Hospital between January and August 2020. The eligibility of participations was established according to the following criteria: (1) cancer confirmed cases in the inpatient ward; (2) patients with only cancer disease; (3) the age of  $\geq 18$  years; (4) questionnaire understanding; and (5) the ability to grant informed acceptance. Patients with different cancer types and stages were included. About 220 patients were invited to participate in this study, and only 170 patients had completed their questionnaire. Only 132 patients were successfully selected in this study, while 38 patients were excluded because they had other diseases associated with cancer.

### 2.3. Procedure

In a department of inpatient, cancer patients who were undergoing chemotherapy were approached. They had received an oral presentation of the study

goal and an explanation about the required information. The participants were requested to sign a consent form. Then, every patient had received a questionnaires packet, including demographic data and clinical status. The forms of DT, PL, and HADS were included in the questionnaires packet according to the national documented forms [19–21]. Next, the accuracy of cancer description was determined by reviewing the reports of medical records. All the participants in this study read the consent form well before signing.

## 2.4. Measures

### 2.4.1. Demographic data and clinical status

Demographic data were obtained from the standardized questionnaire medical and reports reviews (for example, age, gender, marital status, and education), as well as clinical data (for example, type of cancer and cancer stage, the period after diagnosis, and type of treatments had received in the last period).

### 2.4.2. Distress thermometer implementation

NCCN had designed an individual-report screening measure of distress that includes two sections [19,22]. In the first section, patients were requested to choose the score that completely describes their level of distress in the past week, which extends from 0 (no distress) to 10 (severe distress). In the second section, patients are required to describe what they have felt during cancer therapy period through using the problem list (PL) that consists of 40 problems. These problems are classified into five sections (practical problems, family problems, emotional problems, spiritual/religious concerns, and physical problems). Through PL report, the problems might lead to distress among cancer inpatients can be recognized. Moreover, the efficacy of DT to explore psychological distress can be evaluated. Indeed, the advantages as well as specificity and sensitivity were studied.

### 2.4.3. Hospital Anxiety and Depression scale

To assess distress and identify DT optimal cut-off score, the Hospital Anxiety and Depression Scale (HADS) was performed in comparison to DT scale because HADS measures 14 items to evaluate psychological distress; it is characterized by the absence of somatic symptoms that may be due to either psychiatric or medical condition [23]. Therefore, this scale was implemented for patients with cancer. Anyway, every item was measured by participants through selection of one of four options (estimated 0–3) to describe their feeling in the last week. A total score  $\geq 15$  is connotative as significant distress.

#### 2.4.4. Data analysis

Analyses of X2 were performed for variables and categorical data. Pearson was used to investigate the correlation between demographic data, medical variables, and distress. t-tests and variance analysis (ANOVA) were used to analyze continuous variables. Furthermore, the analysis of receiver operating characteristic (ROC) curve was used to determine the optimal DT cut-off score that was defined by the HADS. Furthermore, the relation between personal items in the PL and DT cut-off scores were examined by X2. Moreover, multiple regression analysis was performed to explore the influences of HADS-D and HADS-A scores on the scores of DT. The correlation between distress that defined by DT and that defined by HADS scores were examined using Pearson correlation. All statistical analysis were conducted by SPSS version 12.0 (SPSSInc).

### 3. Results

#### 3.1. Demographic and clinical characteristics

As presented in Si. Table 1, 132 patients with cancer were involved. The mean of the age was 54.77 years (SD = 11.15) since the range was 18–87 years. 56.82% of the participants were females. Most of the participants were married (94.7%). Seventy-five per cent of

Table 1. Frequency distribution of distress thermometer scores.

| Score | No. of patients | %     | Cumulative | %     |
|-------|-----------------|-------|------------|-------|
| 0     | 21              | 15.91 | 21         | 15.91 |
| 1     | 26              | 19.7  | 47         | 35.61 |
| 2     | 22              | 16.67 | 69         | 52.27 |
| 3     | 26              | 19.7  | 95         | 71.97 |
| 4     | 19              | 14.39 | 114        | 86.36 |
| 5     | 10              | 7.58  | 124        | 93.94 |
| 6     | 4               | 3.03  | 128        | 96.97 |
| 8     | 3               | 2.27  | 131        | 99.24 |
| 9     | 1               | 0.76  | 132        | 100   |

the participants were Middle school or lower. In cancer type titles, 27.27% of participants had lung cancer and 24.24% had gastrointestinal (GI) cancer. The analysis of cancer stages in patients showed that 31.82% had stage IV and 18.94% had stage III, according to the physicians responsible for ECOG PS score, the majority of patients were evaluated 87.88%. The analysis of questionnaire timing presented that 15.15% of patients responded to questionnaire before treatment, 2.27% of patients after surgery, 26.52% of patients during chemotherapy treatment, 0.76% of patients after radiotherapy, and 55.3% of patients undergoing combined treatment. Majority of participants had received a combination treatment (55.3%) or chemotherapy (26.52%). Excluded patients were 13.64% of participants because of other combined diseases.

#### 3.2. Cut-off score of DT among cancer inpatients was successfully identified

The frequency distribution of DT scores (0–9) has been presented in Figure 1(a) and Table 1. The calculated average of DT score was 2.56 (standard deviation (SD) = 1.93; N = 132). In general, distress evaluation identified by DT cut-off  $\geq 4$  to recognize the validity of DT cut-off score, the analysis of ROC was performed. As shown in Figure 1(b), ROC curve confirmed the most relevant sensitivity and specificity of the DT compared with HADS established cut-off scores (HADS-T  $\geq 15$ , HADS-A  $\geq 8$ , and HADS-D  $\geq 8$ ). The ROC curves are graphic descriptions of the trade-off between the true-positive rate (sensitivity) and true-negative rate (specificity) for each DT potential cut-off score. In each ROC curve, an area under the curve (AUC) gives the DT cut-off scores an estimation of the discriminative accuracy related to the criterion (HADS-approved cut-off scores). With a range of 1 to

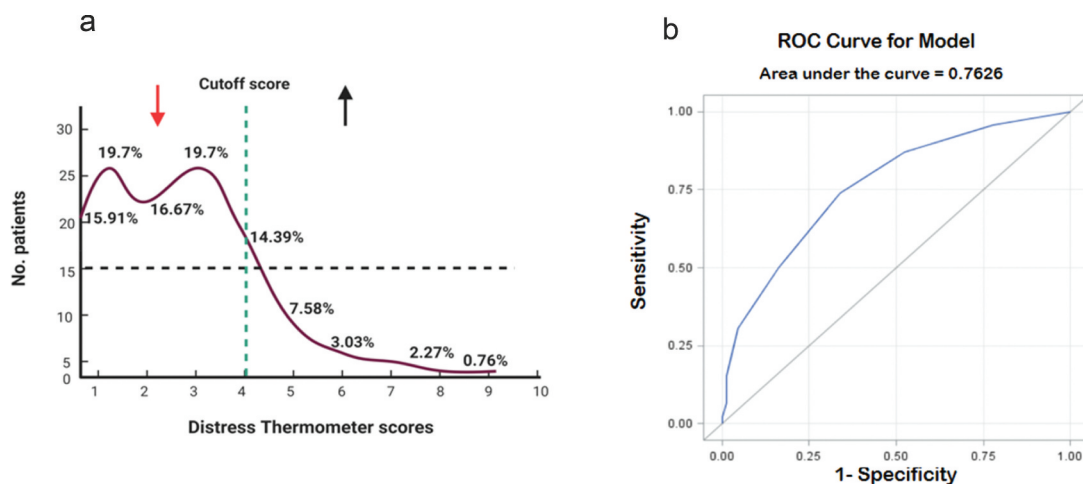


Figure 1. The establishment of DT scores and the frequency distribution of DT scores in participants. (a) The frequency distribution of DT score under and above DT cut-off scores. (b) Receiver operating characteristic curve analysis comparing distress thermometer scores with Hospital Anxiety and Depression scale total score (the cut-off  $\geq 15$ ).

0.5, a test with absolute accuracy relative to the proven criterion represented poor discriminative accuracy to the approved criterion. Hence, results showed that AUC was measured at 0.76 that yielded by a cutoff of 4 with 0.86 sensitivity (true-positive rate) and a 0.56 specificity (true-negative rate) using the HADS-Total (HADS-T) cut-off score as seen in Figure 1(b); an AUC of 0.72 with 0.89 sensitivity and a specificity 0.53 with regard to HADS-A states; and an AUC of 0.76 with a sensitivity of 0.85 and specificity of 0.49 during used HADS-D as cases criterion (Table 2). ROC curve analysis identifies that the optimal cut-off score for DT was  $\geq 4$  for recognizing distress among cancer inpatients.

### 3.3. DT cut-off score showed differences in the evaluation of demographic and clinical variables compared to HADS cut-off score

To examine the relation between DT cut-off score 4 and socio-demographic and clinical variables compared to HADS, chi-square was performed. As seen in Table 3 and Si. Table 2, DT scores showed no significant correlation with any demographic variable except among age categories; the DT cut-off score showed significant differences at 40–49 years and

**Table 2.** Classification rates using a DT cut-off of 4 with respect to HADS-total, HADS-anxiety, and HADS-depression cases.

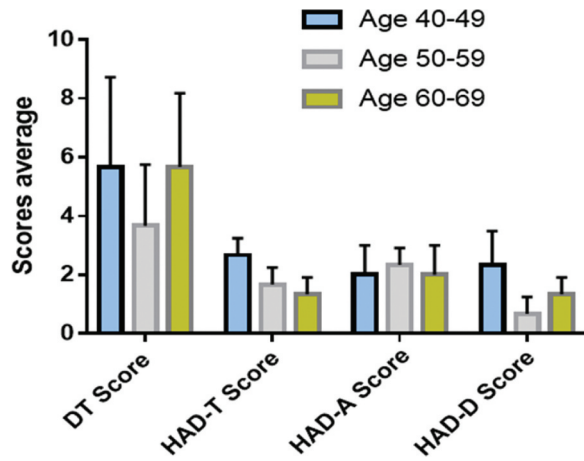
|               | DT                   |                      | Chi-square | p values |
|---------------|----------------------|----------------------|------------|----------|
|               | Below cut-off, N (%) | Above cut-off, N (%) |            |          |
| <b>HAD-T</b>  |                      |                      | 27.48      | <0.0001  |
| Below cut-off | 58 (67.44)           | 28 (32.56)           |            |          |
| Above cut-off | 9 (19.57)            | 37 (80.43)           |            |          |
| <b>HAD-A</b>  |                      |                      | 28.64      | <0.0001  |
| Below cut-off | 60 (66.67)           | 30 (33.33)           |            |          |
| Above cut-off | 7 (16.67)            | 35 (83.33)           |            |          |
| <b>HAD-D</b>  |                      |                      | 17.9       | <0.0001  |
| Below cut-off | 57 (63.33)           | 33 (36.67)           |            |          |
| Above cut-off | 10 (23.81)           | 32 (76.19)           |            |          |

The cut-off used: D  $\geq 4$ , HADS-T  $\geq 15$ , HAD-A  $\geq 8$ , HAD-D  $\geq 8$ . DT, distress thermometer; HADS-T: Hospital Anxiety and Depression Scale total score.

60–69 years old as presented in Figure 2. But the differences in HADS scores were noticed to be non-significant. Furthermore, the analysis of medical variables presented that DT scores were significantly correlated ( $P \leq 0.05$ ) with treatment performance status as seen in Si. Table 2. Further, DT cut-off score of 4

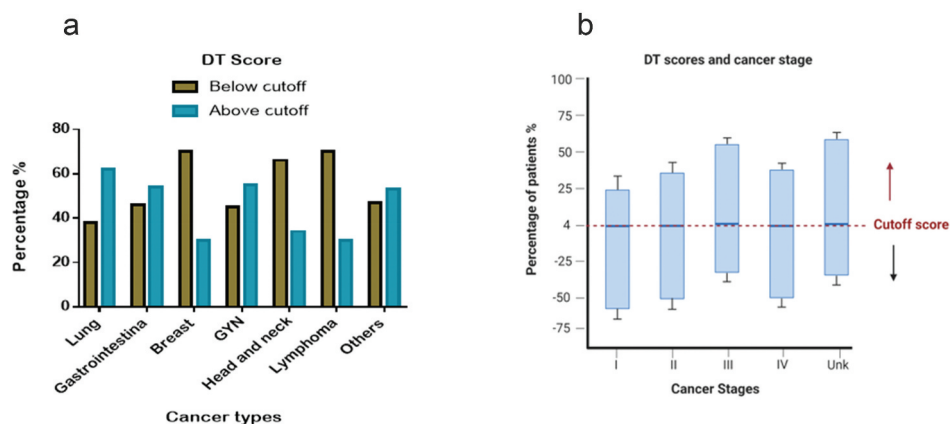
**Table 3.** The relationship between a DT cut-off score of 4 and HADS cut-off score to category demographic and clinical variables.

| Variable                                  | DT score      |               | Chi-square | p values | HAD -T        |               | Chi-square | p values |
|---|---------------|---------------|------------|----------|---------------|---------------|------------|----------|
|   | Below cut-off | Above cut-off |            |          | Below cut-off | Above cut-off |            |          |
| <b>Gender</b>                             |               |               | 0.0006     | 0.98     |               |               | 0.1014     | 0.7501   |
| Male                                      | 29 (50.88)    | 28 (49.12)    |            |          | 38 (66.67)    | 19 (33.33)    |            |          |
| Female                                    | 38 (50.67)    | 37 (49.33)    |            |          | 48 (64.00)    | 27 (36.00)    |            |          |
| <b>Marital status</b>                     |               |               | 0.12       | 0.73     |               |               | 1.6182     | 0.2033   |
| Married                                   | 63 (50.40)    | 62 (49.60)    |            |          | 83 (66.40)    | 42 (33.60)    |            |          |
| Not married (single, divorced, widowed)   | 4 (57.14)     | 3 (42.86)     |            |          | 3 (42.86)     | 4 (57.14)     |            |          |
| <b>Education</b>                          |               |               | 1.02       | 0.60     |               |               | 0.8937     | 0.6396   |
| Middle school or lower                    | 47 (47.47)    | 52 (52.53)    |            |          | 63 (63.64)    | 36 (36.36)    |            |          |
| High school                               | 9 (45.00)     | 11 (55.00)    |            |          | 13 (65.00)    | 7 (35.00)     |            |          |
| College                                   | 8 (84.62)     | 5 (15.38)     |            |          | 10 (76.92)    | 3 (23.08)     |            |          |
| <b>Type of cancer</b>                     |               |               | 7.51       | 0.28     |               |               | 9.5513     | 0.1449   |
| Lung                                      | 14 (38.89)    | 22 (61.11)    |            |          | 22 (61.11)    | 14 (38.89)    |            |          |
| Gastrointestina                           | 15 (46.88)    | 17 (53.13)    |            |          | 16 (50.00)    | 16 (50.00)    |            |          |
| Breast                                    | 12 (70.59)    | 5 (29.41)     |            |          | 14 (82.35)    | 3 (17.65)     |            |          |
| GYN (cervix uteri, corpus uteri, ovarian) | 5 (45.45)     | 6 (54.55)     |            |          | 6 (54.55)     | 5 (45.45)     |            |          |
| Head and neck (NPC, oral, thyroid)        | 6 (66.67)     | 3 (33.33)     |            |          | 8 (88.89)     | 1 (11.11)     |            |          |
| Lymphoma                                  | 7 (70.00)     | 3 (30.00)     |            |          | 7 (70.00)     | 3 (30.00)     |            |          |
| Others                                    | 8 (47.06)     | 9 (52.94)     |            |          | 13 (76.47)    | 4 (23.53)     |            |          |
| <b>Stages of cancer</b>                   |               |               | 6.91       | 0.14     |               |               | 4.2972     | 0.3673   |
| 1   | 8 (72.73)     | 3 (27.27)     |            |          | 10 (90.91)    | 1 (9.09)      |            |          |
| 2   | 13 (59.09)    | 9 (40.91)     |            |          | 14 (63.64)    | 8 (36.36)     |            |          |
| 3   | 9 (36.00)     | 16 (64.00)    |            |          | 15 (60.00)    | 10 (40.00)    |            |          |
| 4   | 24 (57.14)    | 18 (42.86)    |            |          | 25 (59.52)    | 17 (40.48)    |            |          |
| Unknown                                   | 13 (40.63)    | 19 (59.38)    |            |          | 22 (68.75)    | 10 (31.25)    |            |          |
| <b>Treatment in the past</b>              |               |               | 0.01       | 0.94     |               |               | 0.2441     | 0.6213   |
| Yes                                       | 57 (50.89)    | 55 (49.11)    |            |          | 72 (64.29)    | 40 (35.71)    |            |          |
| No  | 10 (50.00)    | 10 (50.00)    |            |          | 14 (70.00)    | 6 (30.00)     |            |          |
| <b>Chemotherapy in the past</b>           |               |               | 0.09       | 0.76     |               |               | 0.2454     | 0.6204   |
| Yes                                       | 17 (48.57)    | 18 (51.43)    |            |          | 24 (68.57)    | 11 (31.43)    |            |          |
| No  | 50 (51.55)    | 47 (48.45)    |            |          | 62 (63.92)    | 35 (36.08)    |            |          |
| <b>Combined Treatment</b>                 |               |               | 0.46       | 0.50     |               |               | 0.8851     | 0.3468   |
| Yes                                       | 39 (53.42)    | 34 (46.58)    |            |          | 45 (61.64)    | 28 (38.36)    |            |          |
| No  | 28 (47.46)    | 31 (52.54)    |            |          | 41 (69.49)    | 18 (30.51)    |            |          |
| <b>Combined disease</b>                   |               |               | 0.00       | 0.94     |               |               | 2.1074     | 0.1466   |
| Yes                                       | 9 (50.00)     | 9 (50.00)     |            |          | 9 (50.00)     | 9 (50.00)     |            |          |
| No  | 58 (50.88)    | 56 (49.12)    |            |          | 77 (67.54)    | 37 (32.46)    |            |          |



**Figure 2.** The analysis of the relation between a DT cut-off score of 4 and age categories compared to HADS measures showed that age categories (40–49 & 60–69) years are susceptible to get DT above the cut-off score compared to other age groups. HADS measures did not identify any significant differences. Suggesting that DT score could be more sensitive in measuring the relation of some demographic data with distress.

was independent of other clinical variables like a type of cancer and the stage of cancer or chemotherapy intervention. As presented in Figure 3(a), the DT scores showed no significant relation between DT and the type of cancer. Regarding scores of HADS, only scores of HADS-A showed a significant correlation ( $P \leq 0.05$ ) with the type of cancer; especially, gastrointestinal and lung cancer that stimulated high anxiety levels compared to patients with other cancer types (Chi-Square = 14.60;  $P \leq 0.02$ ). Although the analysis of relationship between DT scores and cancer stage showed no significant relation, we noticed that patients with cancer at stage III or unknown stage presented scores above the cut-off as seen Figure 3(b).



**Figure 3.** (a) presents the percentage of distress associated with cancer types. This analysis presented the percentage of patients rated up and down the cut-off score of DT. (b) the analysis of up and down DT cut-off scores distribution according to cancer stage. It was noticed that stage III and Unk stage showed increasing in the DT scores above the cut-off scores but the statistical analysis showed no significant differences.

### 3.4. DT cut-off score showed high performance to evaluate the items listed in PL

General frequencies of items of PL were presented as the following: insurance (72.73%), child care (34.1%), transportation (31.82%), housing (15.15%), and work/school (12.12%) see Si. Table 3. With regard to a family section ( $N = 61$ ), cases that deal with children are 28%, while 23.5% are dealing with partners. Regarding an emotional object ( $N = 118$ ), the most commonly checked objects were worry (46.97%), nervousness (35.61%), sadness (12.12%), loss of interest in usual activities (10.6%), depression (9.1%), fears (5.3%), and feeling lonely (5.3%). In the physical problems ( $N = 115$ ), the eight most commonly confirmed items were sleep (38.6%), fatigue (33.3%), constipation (22.7%), tingling in hands/feet (21.1%), memory/concentration (21.9%), pain (22.7%), nausea (17.4%), and eating (15.7%).

In addition, the relation between a cutoff score of DT and items in the PL showed significant differences in the category of practical ( $P \leq 0.05$ ) as presented in Si. Table 3 as well as the participant who scored  $\geq 4$  on the DT had more problems with childcare (62.2%), housing (70%), and transportation (71%). In a family category, the DT cut-off ( $\geq 4$ ) was significantly correlated with two of three listed problems ( $P \leq 0.05$ ). These participants had more problems in dealing with both partners (32%) and children (35%). About the category of emotional, the cut-off score of DT was associated with most items significantly ( $P \leq 0.05$ ). Moreover, patients who scored  $\geq 4$  on the DT scale showed more likely to describe problems with depression, fears, sadness, nervousness, and worry. Finally, regarding physical problems, the DT cut-off score was significantly associated with patients who were likely to confirm problems with breathing, changes in urination, constipation, eating, fatigue, feeling swollen, pain, and tingling in hands/feet.

## 4. Discussion

Psychosocial distress is a common problem in patients with cancer [5]. Early evaluation of distress enables appropriate psychosocial support and precise intervention by health-care professionals [24]. The implementation of DT scale among cancer outpatients contributed to an early determination of distress sources and proper supportive care [25]. However, the determination of optimal DT cut-off score among cancer inpatients and the implementation of the DT scale for screening distress sources have not been reported. This study explores a practical cut-off score of DT among cancer inpatients and provides clinical evidence about the efficacy of DT to screen distress sources for cancer inpatients. The importance of distress source determination lies in the proper psychological intervention, which can contribute to improve a response to cancer therapy. The determined DT cut-off score among cancer inpatients in this study showed an optimal sensitivity and specificity. DT cut-off score 4 was realized by the HADS-T cut-off scores to recognize a clinically meaningful distress level and explore a specific source of distress. Some previous studies reported that the optimal DT cut-off score is 5 according to the NCCN distress management guidelines [26], but we found other studies that support the same optimal cut-off score of DT we found in this study [27–29]. Our calculations for cancer inpatients outcomes confirmed that the optimal cut-off of DT among cancer inpatients is 4. Moreover, cancer inpatients who scored  $\geq 4$  on the DT were significantly more likely to have a poorer performance status. As expected, the participant who scored  $\geq 4$  on DT were significantly more likely to inform a set of concerns that involved practical problems, emotional problems, family problems, and physical problems. These kinds of problems require urgent medical intervention and care. Hence, DT cut-off can explore the supportive needs of cancer inpatients.

Furthermore, the analysis of ROC showed an AUC of 0.76, suggesting very good discriminative precision according to the HADS-T score that was found similar to the earlier confirmed values reported by Jacobsen and colleagues [30], Grassi et al. [31], and Shim et al. [29]. Furthermore, according to cut-off score  $\geq 4$ , the overall distress rate was 41.2%, which was a little bit lower than the rate detected in patients with multidisciplinary lung cancer 61.6% [32] and patients with cancer in Turkey 59.4% [27]. Interestingly, the DT cut-off of 4 against the HADS determined an optimal sensitivity of 0.86 and specificity of 0.56 compared to sensitivity results of previous reports of 68% [30], 59% [29], and 61% [33]. On the other hand, the relationship between scores  $\geq 4$  on DT and poorer performance status was observed. Earlier studies confirmed the significant relationships between poorer performance status and

elevated psychological distress [34,35]. Moreover, Stark pointed out that female sex and negative aspects of social support were associated with anxiety disorder in multivariate analyses among cancer patients [36]. And Duan mentioned a possible different result for each gender when the analysis is relate to chronic pain and depression [37]. In this study, age groups 40-49 and 60-69 years old showed scores above DT cut-off compared to other groups. These results pointed out that the age of cancer inpatients could play a role in the development of psychological distress. We expect that the increase of DT scores due to the big size of tested community compared to other previous studies. In addition, other demographic data showed no significant relation with DT scores, which is on the same line with previous studies [27,38].

### 4.1. Study limitations

In this study, there were some limitations that should be noticed. First, the study sample was limited with regard to socioeconomic state and education. Thus, some significant subgroup differentiation may have gone undetected due to sample size and its heterogeneity. Furthermore, a study with larger sample size is needed to conquer this limitation. In addition, the response rate was comparatively lower with probable sample inclination and, thus, more studies are needed.

### Authors' contributions

A.A, conception, design, data acquisition and data analysis; M.A, data analysis, results interpretation and manuscript drafting; S.Y & H. P supervised the whole work, revised the manuscript and approved it.

### Data availability

The authors declare that all the analyzed data were included in the main content of this article and supplementary data. Curd data are also available by sending an email to the corresponding author.

### Disclosure statement

The authors declare that there are no financial or non-financial conflicts of interests related to this work.

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