Swedish Version of the Distress Thermometer: Validity Evidence in Patients With Colorectal Cancer

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Abstract

Background: The objective of this study was to validate the NCCN Distress Thermometer (DT), including the accompanying Problem List (PL), in a Swedish population of patients diagnosed with colorectal cancer (CRC). **Methods:** A total of 488 patients diagnosed with CRC completed the DT/PL and EORTC core quality-of-life questionnaire (QLQ-C30) before surgery. Construct validity of the PL was analyzed using a confirmatory factor analysis. Internal consistency reliability (ICR) was tested using Cronbach's alpha coefficient. Correlations between the reported PL areas and QLQ-C30 function scales were used to explore convergent validity. Discriminant validity was examined by evaluating associations between the DT and QLQ-C30 measures of overall health-related quality of life (HRQoL). **Results:** Findings showed that the Swedish translation of the DT/PL is consistent with the original English version. The DT has good ICR, with the total number of reported problems significantly correlating with DT scores ($r=0.67$; $P<.001$). Analysis of convergent validity indicated that the PL areas significantly correlated with QLQ-C30 function scales, with emotional problems showing the highest correlation ($r=0.76$; $P<.001$), and item-level correlation analyses showed significant correlations between symptoms. There was also good discriminant validity between the DT and the QLQ-C30 in terms of HRQoL, including overall health status ($r=-0.49$; $P<.001$) and overall quality of life ($r=-0.57$; $P<.001$). Furthermore, there was good discriminant validity between the DT and QLQ-C30 regarding poor, moderate, and excellent HRQoL. **Conclusions:** These findings provide validity evidence regarding the DT, including the PL. Findings also show that the DT has good potential for screening distress-related practical, family, emotional, and physical problems during the cancer trajectory in Swedish-speaking patients. Additionally, the DT seems to be an effective screening tool to detect patients with poor, moderate, and excellent HRQoL.

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There is increasing recognition that psychosocial care, with its goal of relieving emotional distress and promoting well-being, is an essential component of the comprehensive care of patients diagnosed with cancer. Heightened distress is common¹ and is associated with worse health-related quality of life (HRQoL),² poorer adherence to treatment recommendations,³ and poorer

survival in patients with cancer.⁴ Yet, evidence indicates that heightened distress often goes unrecognized.⁵

NCCN recommends that all patients be routinely screened for distress at appropriate intervals during the cancer trajectory,⁶ and the Distress Thermometer (DT) has been shown to be an effective screening tool in identifying distress in patients with cancer.^{6,7} The one-

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item DT was originally published by Roth et al⁸ in 1998, and appears in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) accompanied by a Problem List (PL), which categorizes sources of distress. The DT is widely used in the supportive and palliative care of patients with cancer across a diverse range of settings and various populations,⁹ and is systematically validated across countries and cultures.^{10–15} However, there are several challenges to translating these instruments. One such challenge with the DT is the translation of the core concept itself; for example, there is no relevant corresponding Swedish term for *distress*.

Several studies^{12,16,17} have tested the validity of the DT with the Hospital Anxiety and Depression Scale (HADS), also using HADS to determine specificity and sensitivity for identifying clinical cases.¹⁸ Based on a validation study examining a Swedish translation of an earlier version of the DT (version 1.2004) in relation to HADS, Thalén-Lindström et al¹⁷ suggested that, with a cutoff threshold for significance of ≥ 4 , the DT is valid for screening purposes and has the ability to measure changes in distress over time.

Although most studies tested the validity of the DT, few studies have validated the PL. The PL consists of a list of 39 items regarding responses to cancer and its treatment, which are categorized into 5 PL areas measuring practical, family, emotional, spiritual/religious, and physical problems.⁹ The PL also includes 1 open-ended item that allows respondents to indicate other problems not included in the list. Less is known about how these problems are associated with each other. To the best of our knowledge, no studies have validated the PL using the EORTC core quality-of-life questionnaire (QLQ-C30) function scales.

In patients with colorectal cancer (CRC), significant negative relationships have been found between mental health outcomes, as measured by HADS, and HRQoL, as measured using the QLQ-C30.¹⁹ However, the association between distress, measured with the DT, and HRQoL, measured by QLQ-C30, is less known, as is whether the DT can identify individuals with poor, moderate, or excellent HRQoL.

The main objectives of this study were to examine measurement validity and reliability with respect to the DT/PL in a Swedish population of patients diagnosed with CRC. We specifically examined construct validity, internal consistency reliability (ICR),

and convergent and discriminant validity, by addressing the following questions:

- Do the PL items cluster in a manner that is consistent with the PL areas?
- What is the ICR of the PL areas and what are their correlations with the DT?
- How do the PL items correlate with the HRQoL domains of the QLQ-C30?
- To what extent does the DT distinguish groups of people with poor, moderate, or excellent HRQoL?

Methods

Ethical Approval

Ethical approval was granted by The Regional Ethical Review Board in Gothenburg, Sweden (Dnr:2012-08-13; T264-14).

Sample and Setting

The study sample was included in a large person-centered information and communication intervention among patients scheduled for elective CRC surgery. Patients were consecutively enrolled, and data were collected presurgery, including the intervention group and controls. Study exclusion criteria were nonelective surgery, metastasis, preoperative chemotherapy, long-term preoperative radiation, diagnosis of benign tumors postsurgery, reduced cognitive function, and lacking ability to communicate in Swedish. Patient sociodemographic and clinical characteristics are presented in Table 1.

Data Collection

Eligible patients received oral and written study information from nurses and surgeons at the hospitals' outpatient clinics. Following their written consent, participants completed questionnaires prior to surgery, measuring HRQoL, preparedness, distress, well-being, and coping. Medical diagnosis was obtained from patient medical records, whereas demographic variables were included in the questionnaire. Patient-reported outcome measures were the DT/PL and QLQ-C30.

Measures

The DT is a one-item, self-reported measure for distress. Respondents were instructed to indicate how

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Table 1. Patient Sociodemographic and Clinical Characteristics (N=488)

Characteristics	%
Mean age (range), y	68 (32–93)
Male/Female	45/55
Partnered/Single	76/24
Married/Unmarried/Widow(er)	62/26/11
Elementary/High school/University/Other	28/24/33/14
Employed/Retired	32/67
Birth country: Sweden/other country	86/14
Colon/Rectal cancer	58/41

distressed they felt in the previous week using a visual analog scale ranging from 0 (“no distress”) to 10 (“extreme distress”). To identify the prevalence of distress, we used a cutoff score of 4.⁶ The DT is accompanied by a PL categorized into 5 areas: practical, family, emotional, spiritual/religious, and physical. The items for each 5 areas are listed in Table 2. Respondents were asked to indicate whether they have experienced any of the problems during the previous week. Although each PL item has 2 checkboxes to indicate “yes” or “no,” many people only checked off “yes” for problem items while *not* checking off “no” for other problem items. For our analyses, we assumed missing responses to any of the items listed on the PL indicated “no” for those who responded to at least one of the items.

For this study, the first author (E.K.S.) and a health-care manager with expertise in cancer care quality development, translated the English version of the DT/PL published at that time (version 2.2013) into Swedish using a standard forward-translation procedure.²⁰ These 2 versions were discussed and discrepancies solved through mutual consensus. The Swedish version was then submitted to 2 independent bilingual translators for back translations into English, and the original English version and the back-translated version were then analyzed for further discrepancies. When consensus was established, with an agreement to use the English term *distress*, a Swedish translation of the definition of distress according to NCCN was included. The Swedish approved translation of the NCCN DT/PL Screening Tool from the NCCN Guidelines for Distress Management is shown in Figure 1.

The DT/PL, as well as the definition of distress, were then evaluated in a pilot study in which 30 patients, diagnosed with different types of cancer (lung,

Table 2. Frequencies and Loadings for PL Items (N=459)^a

Problems/Concerns	Frequency	Loading ^b
Practical		
PL-1: Child care ^c	0.2	
PL-2: Housing	2.0	0.41
PL-3: Insurance/Financial	6.8	0.68
PL-4: Transportation	4.8	0.52
PL-5: Work/School	8.7	0.68
PL-6: Treatment decisions	7.8	0.85
Family		
PL-7: Dealing with children	3.1	0.74
PL-8: Dealing with partner	4.8	0.82
PL-9: Ability to have children	0.9	0.44
PL-10: Family health issues	10.5	0.77
Emotional		
PL-11: Depression	8.7	0.76
PL-12: Fears	25.5	0.86
PL-13: Nervousness	31.6	0.80
PL-14: Sadness	34.9	0.87
PL-15: Worry	61.0	0.88
PL-16: Loss of interest in usual activities	17.4	0.69
Spiritual/Religious		
PL-17	6.5	0.71
Physical		
PL-18: Appearance	2.0	0.78
PL-19: Bathing/Dressing	2.0	0.80
PL-20: Breathing	5.0	0.65
PL-21: Changes in urination	7.8	0.39
PL-22: Constipation	17.2	0.42
PL-23: Diarrhea	28.3	0.40
PL-24: Eating	8.5	0.62
PL-25: Fatigue	43.4	0.80
PL-26: Feeling swollen	12.6	0.59
PL-27: Fevers	2.2	0.44
PL-28: Getting around	13.9	0.68
PL-29: Indigestion	10.9	0.66
PL-30: Memory/Concentration	18.7	0.60
PL-31: Mouth sores	3.5	0.29
PL-32: Nausea	9.4	0.62
PL-33: Nose dry/congested	8.3	0.42
PL-34: Pain	19.6	0.70
PL-35: Sexual	10.7	0.54
PL-36: Skin dry/itchy	15.3	0.48
PL-37: Sleep	34.6	0.51
PL-38: Substance abuse ^c	0.2	
PL-39: Tingling in hands/feet	8.9	0.36

Abbreviations: CFA, confirmatory factor analysis; PL, Problem List.

^a29 people did not complete the PL.

^bStandardized loadings of CFA.

^cItem was excluded from the CFA because of extremely low frequency.

hematologic, gynecologic, and breast, and malignant melanoma), tested and confirmed the applicability of the Swedish version, including the use of the term *distress*. In the present study, a translation of the NCCN definition of distress was presented to participants before they were asked to respond to the DT/PL.

The QLQ-C30 was used to measure domains of HRQoL. This questionnaire was specifically developed to assess quality of life (QoL) in patients with cancer participating in clinical trials.²¹ The questionnaire consists of 5 function scales (physical, role, cognitive, emotional, and social), 3 symptom subscales (fatigue, pain, nausea/vomiting), and 6 single-item scales (dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties). The QLQ-C30 also generates a global health status based on 2 items regarding respondents' experiences of health (question [Q] 29) and QoL (Q30) during the past week. The QLQ-C30 scores were calculated according to the algorithm of the QLQ-C30 scoring manual.²² The reliability and validity of the QLQ-C30 have been established in several studies.^{21,23}

Statistical Analyses

Construct validity was explored by conducting a confirmatory factor analysis (CFA) using mean- and

variance-adjusted weighted least squares estimation and tetrachoric correlations to accommodate the binary variables.²⁴ We specifically examined whether the PL items cluster in a way that corresponds with the 5 PL areas. Two items (child care and substance abuse) were excluded from this analysis because they were endorsed by only 1 person. Well-established CFA guidelines were followed.²⁵ The CFA model was specified by uniquely associating the items (problems) of each area with 1 of 5 correlated latent factors (each representing 1 area). The variances of the latent factors were fixed at 1 for purposes of model identification. For the area that had only 1 factor, the item loading was fixed at 1. The following criteria were used to evaluate model fit: (1) a root mean square error of approximation (RMSEA) <0.06 indicated good model fit and between 0.06 and 0.08 indicated adequate fit, and (2) a comparative fit index (CFI) >0.95 indicated good model fit.^{26,27}

The ICR of the 4 PL areas (spiritual/religious area was excluded because it consists of only 1 item) were assessed based on the ordinal version of Cronbach's alpha coefficient, which is appropriate for both binary and ordinal items, using the estimates of the CFA models with correlated latent factors.²⁸ An $\alpha > 0.70$ was considered satisfactory for internal con-

NCCN National Comprehensive Cancer Network®

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)
Swedish Edition: Distress Management Version 2.2013

SCREENINGSTRUMENT FÖR ATT MÄTA DISTRESS

Instruktioner: Börja med att ringa in den siffran (0-10) som bäst beskriver hur mycket distress du har upplevt den senaste veckan, inklusive idag.

Extrem distress

10
9
8
7
6
5
4
3
2
1
0
Ingen distress

Därefter, var snäll och ange om något av följande har varit ett problem för dig under den senaste veckan, inklusive idag. Markera antingen JA eller NEJ för varje alternativ.

Ja	Nej	Praktiska problem	Ja	Nej	Fysiska problem
☐	☐	Barnomsorg	☐	☐	Utseende
☐	☐	Bostad	☐	☐	Hygien/påklädning
☐	☐	Ekonomi/försäkringar	☐	☐	Andning
☐	☐	Transport	☐	☐	Förändrad uriner
☐	☐	Arbete/studier	☐	☐	Förstopning
☐	☐	Beslut om behandling	☐	☐	Diarré
☐	☐	Familjerelaterade problem	☐	☐	Åtsvårigheter
☐	☐	Relation till barn	☐	☐	Trötthet
☐	☐	Relation till partner	☐	☐	Känner mig svullen
☐	☐	Möjligheten att kunna få barn	☐	☐	Feber
☐	☐	Hälsoproblem inom familjen	☐	☐	Rörighet
☐	☐	Känslomässiga problem	☐	☐	Matsmältning
☐	☐	Depression	☐	☐	Minne/koncentration
☐	☐	Rädsla	☐	☐	Munsår
☐	☐	Nervositet	☐	☐	Illamående
☐	☐	Nedstämdhet	☐	☐	Torr/tilltäppt näsa
☐	☐	Oro	☐	☐	Smärta
☐	☐	Förlust av intresse för vardagliga aktiviteter	☐	☐	Sexuella problem
☐	☐	Existentiella/religiösa funderingar	☐	☐	Torr hud/klåda
			☐	☐	Sömn
			☐	☐	Missbruk
			☐	☐	Stickningar i händer/fötter

Övriga problem: _____

DIS-A

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Figure 1. Distress screening tool Swedish version 2.2013.

sistency.²⁹ Additionally, we explored the correlation between the total number of reported problems and the DT scores.

Convergent and discriminant validity were explored by examining correlations between the reported PL areas and EORTC function scales. Convergent validity tested whether these subscales, which were expected to be related, were in fact related. Discriminant validity tested whether the construct “Distress” (DT) had low or moderate correlation to “Global Health and QoL” (QLQ-C30). Spearman’s correlations were used to accommodate the ordinal data.

The QLQ-C30 global health status (Q29) was used to create the following groups: poor health status (scores 1–2), moderate health status (scores 3–5), and excellent health status (scores 6–7). Similarly, the discriminant validity was examined with respect to QoL using the QLQ-C30 global QoL (Q30). For all analyses, $P < .05$ was considered statistically significant.

Results

A total sample of 488 eligible participants were included in the study. The DT/PL form was missing for 6% of the patients ($n=29$), yielding a 94% response rate. Partial missing data (missing of single items) varied between 1% and 3% except for the item “Substance abuse,” for which missing data was 4%. A total of 459 patients responded to at least one of the PL items, 422 responded to the DT (37 were excluded due to partial missing data), and 476 responded to the QLQ-C30 questionnaire.

A prevalence of distress (DT >0) was reported by 86% of patients; 59 patients (14%) reported a DT score of 0, 233 (55%) reported a DT score between 0 and 4, and 130 (31%) reported a DT score >4 .⁶

Construct Validity

Percentages of respondents endorsing the PL items ranged from 0.2 for PL-Child care (item 1) and PL-Substance abuse (item 38) to 61.0 for PL-Worry (item 15). A CFA of the remaining 37 items and 5 correlated latent factors resulted in acceptable overall model fit ($\chi^2 [df]=778 [620]$; RMSEA=0.024; CFI=0.93; $n=461$). Factor loadings were <0.40 for PL-Changes in urination (item 21), PL-Mouth sores (item 31), and PL-Tingling in hands/feet (item 39),

with the remaining factor loadings ranging from 0.40 for PL-Diarrhea (item 23) to 0.88 for PL-Worry (item 15) (Table 2). The latent factor correlations ranged from 0.24 to 0.74. The smallest and not statistically significant correlations were for “spiritual/religious concerns” with “practical problems” and “family problems” (Table 3).

Internal Consistency Reliability

The ICR ranged from 0.77 for practical problems to 0.92 for emotional problems. There was a moderate correlation between the DT and number of reported problems ($r=0.67$; $P < .001$) (Figure 2).

Convergent Validity

The number of emotional problems on the PL showed the highest correlation ($r=0.76$) with the emotional functioning scale on the QLQ-C30 (Table 4). The number of physical problems correlated with QLQ-C30–physical functioning ($r=0.53$), QLQ-C30–pain ($r=0.55$), QLQ-C30–social functioning ($r=0.51$), QLQ-C30–cognitive functioning ($r=0.50$), and QLQ-C30–emotional functioning ($r=0.44$). The number of family-related problems (according to the PL) correlated with all of the QLQ-C30 subscales, but correlations were not very strong, ranging between 0.17 and 0.30.

The number of practical problems on the PL correlated moderately with the 4 QLQ-C30 functioning subscales and the pain scale, with correlations ranging between 0.17 and 0.35. In addition, the DT correlated satisfactorily with QLQ-C30 emotional functioning ($r=0.74$), cognitive functioning ($r=0.42$), and social functioning ($r=0.42$) subscales. All cor-

Table 3. Correlations Among Problem List Areas^{a,b} (N=459)

	Practical	Family	Emotional	Spiritual/ Religious	Physical
Practical					
Family	0.74*				
Emotional	0.62*	0.52*			
Spiritual/ Religious	0.27	0.24	0.65*		
Physical	0.72*	0.54*	0.61*	0.44*	

^aPearson correlations based on the estimated confirmatory factor analysis model.

^b29 people did not complete the Problem List.

* $P < .01$.

Figure 2. Correlations between the Distress Thermometer (DT) and number of reported problems.

relations were statistically significant ($P<.001$) (Table 4).

Because the PL does not have natural corresponding subscales to the QLQ-C30, some correlation analyses were performed at the item level. PL-Fatigue (item 25) correlated well with QLQ-C30–Fatigue (Q18; $r=0.66$); PL-Nausea (item 32) correlated with QLQ-C30–Nausea (Q14; $r=0.60$); PL-Pain (item 34) correlated with QLQ-C30–Pain (Q9; $r=0.63$, and Q19; $r=0.61$, respectively); PL-Sleep (item 37) correlated with QLQ-C30–Insom-

Table 4. Correlations of DT/PL Areas With EORTC Function Scales					
EORTC ^a	PL Areas				DT 0–10 ^b
	Emotional	Physical	Family	Practical	
Emotional functioning	0.76*	0.44*	0.23*	0.35*	0.74*
Physical functioning	0.23*	0.53*	0.19*	0.22*	0.24*
Cognitive functioning	0.43*	0.50*	0.30*	0.33*	0.42*
Social functioning	0.41*	0.51*	0.20*	0.32*	0.42*
Pain	0.26*	0.55*	0.17*	0.27*	0.26*

Only 4 of the 5 PL areas were included. The spiritual/religious area consists of only 1 item (yes/no), whereas the other PL areas include several items, yielding scores (count of problems) that could be checked for correlation to the corresponding EORTC-function scales. None of the EORTC-function scales correspond to the spiritual/religious dimension.
Abbreviations: DT, Distress Thermometer; PL Problem List.
^aEORTC QLQ-C30 function scales.
^bDT visual analog scale of 0–10.
* $P<.001$. All correlations (r) were statistically significant.

nia (Q11; $r=0.69$), PL-Constipation (item 22) correlated with QLQ-C30–Constipation (Q16; $r=0.71$); PL-Diarrhea (item 23) correlated with QLQ-C30–Diarrhea (Q17; $r=0.74$); and PL-Insurance/Financial (item 3) correlated with QLQ-C30–Financial (Q28; $r=0.59$) ($P<.001$) (Table 5).

Discriminant Validity

As expected, DT scores were associated with QLQ-C30 overall health status (Q29; $r=-0.492$; $P<.001$; Figure 3) and QoL (Q30; $r=-0.569$; $P<.001$; Figure 4). There was a significant amount of dispersion with respect to DT scores at poor, moderate, and excellent overall HRQoL, which suggests good discriminant validity between the 2 measures.

Discussion

To our knowledge, this is the first study that has performed a CFA to validate the DT and accompanying PL. The CFA suggests that the PL items correspond acceptably well with the structure of the 5 correlated PL areas.

Our findings using the Swedish translation of the DT are consistent with those of the original English version. These results are in accordance with other studies aimed at translating and validating the DT in patients with cancer in different countries and cultures.¹⁵ Additionally, our results showed that the PL has good ICR. The total number of reported problems significantly correlated with DT scores, suggesting that there is good internal consistency in the instrument (ie, high numbers of symptoms/problems correlated with high scores on the DT). This could be considered an aspect of internal consistency of the questionnaire, because 2 different parts on the questionnaire, measuring the same construct, clearly correlate with each other.

The convergent validity, analyzed as the correlation between the PL areas and QLQ-C30 function scales, indicated that emotional problems (PL) showed the highest correlation with emotional functioning (QLQ-C30). Likewise, physical problems were associated with physical functioning (QLQ-C30). Also, item-level correlation analyses showed significant correlations between symptoms, financial difficulties, work/daily activities, and cognitive function. Others have examined the DT with respect to the HADS,^{12,16–18} and our study complements that

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Table 5. Correlations Between PL Items and Corresponding EORTC Symptom Queries

Variables	PL Item	EORTC Symptom Questions	Correlation Coefficient ^a
Insurance/Financial difficulties	3	28	0.59*
Work/Daily activities	5	6	0.36*
Cognitive function ^b	30	20, 25	0.34*, 0.61*
Nausea	32	14	0.60*
Fatigue	25	18	0.66*
Breathing	20	8	0.32*
Diarrhea	23	17	0.74*
Appetite	24	13	0.49*
Constipation	22	16	0.71*
Pain ^b	34	9,19	0.63*, 0.61*
Sleep	37	11	0.69*

Abbreviation: PL, Problem List.

^aSpearman's coefficient.^bEORTC variables consisting of 2 items (cognitive function and pain), and each item was significantly correlated with the respective PL item.* $P < .001$. All correlations were statistically significant.

research by examining the DT in relation to other dimensions of HRQoL.

Research in psycho-oncology has made evident that cancer care involves more than clinical treatment of the disease, and patients' experiences of psychosocial concerns has gained a greater attention within the cancer community. Cancer survivors have impaired HRQoL, and a substantial proportion of these patients experience distress and may ben-

efit from psychological interventions.³⁰ Our study results suggest good discriminant validity between the DT and QLQ-C30, with a significant distribution, regarding poor, moderate, and excellent HRQoL. Our findings regarding the significant association between responses to the DT and HRQoL measured by the QLQ-C30 illustrate that the DT has the potential to identify individuals in need of interventions to improve their HRQoL.

Finally, the present study used the English term *distress*. Originally, this term was chosen for its lack of associated psychological implications and ability to be defined and measured.³¹ As opposed to a single physical or psychological symptom, this broad concept highlights its multifactorial etiology and multidimensionality. Instead of using adjacent Swedish words, which would not capture the core concept "distress," we provided a translation of the definition.

Limitations

Although we found support for the use of DT/PL in a large sample of Swedish patients diagnosed with CRC, measurement validity with respect to other Swedish cancer populations are unknown. However, the DT has been successfully evaluated in a variety of settings and in patients with different cancer diagnoses.¹⁵ It would have been desirable to test the repeatability over time with a test/retest method. Therefore, further prospective research applying a test/retest of the DT/PL is recommended.

Figure 3. Association between distress and overall health. Abbreviation: DT, Distress Thermometer.

Figure 4. Association between distress and quality of life. Abbreviation: DT, Distress Thermometer.

Conclusions

Due to the importance of cancer-related distress, its high prevalence, and its significant impact on patient HRQoL, the availability of psychometrically sound screening instruments is critical. Our analysis provides general support for the measurement validity of the DT/PL in a sample of patients scheduled for CRC surgery. Further, the results pertaining to the Swedish translation of the DT indicate its potential

usefulness for evaluating distress during the cancer trajectory in Swedish-speaking patients. In addition, our findings indicate that the DT can also be used as a rapid screening tool to identify individuals in need of interventions to improve their HRQoL.

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