Research Paper

The validity of the distress thermometer in patients with musculoskeletal tumors

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HIGHLIGHTS

- About three in four patients with musculoskeletal tumors have relevant psychological distress.
- A Distress Thermometer score ≥ 5 indicates moderate or severe psychological distress.
- A strong relationship between patient and care team is associated with less psychological distress.

ARTICLE INFO

ABSTRACT

Background: Visits to an outpatient cancer clinic represent a challenging situation for patients, which can trigger anxiety and helplessness in those affected. It is important to identify patients with high psychological distress as early as possible in order to provide them with supportive psychological interventions. The aim of this study was to validate the Distress Thermometer (DT), a widely used screening for distress, in a cohort of patients with musculoskeletal tumors and to explore associations between distress, treatment satisfaction and health literacy.

Methods: All patients presenting to a University outpatient clinic for musculoskeletal cancers were asked to complete a set of questionnaires including the DT), the Hospital Anxiety and Depression Scale (HADS) as a comparison scale, the Patient Satisfaction with Comprehensive Cancer Care (SCCC) and European Health Literacy Survey Questionnaire (HLS-EU-Q16).

To assess the sensitivity and specificity of the DT in a cohort of patients with musculoskeletal tumors, we compare the performance of the DT in relation to an established screener for anxiety and depression using receiver operating characteristics (ROC) analyses.

Results: A total of 120 patients (age 58 ± 18, 51% female) were analyzed. Patients reported a mean DT of 5.0 (SD 2.3, range, 0 to 10). Eighty-six patients (71.7 %) had a DT score ≥ 5 indicating moderate or severe psychological distress.

The mean total HADS score (scale 0 to 42 points) was 11.7 (SD 7.6, range, 0 to 32) with a HADS score of ≥ 15 in 29.2% of patients. The DT correlated moderately with anxiety and depression (HADS total $r = 0.48$, $p < 0.001$), while the correlation with depression (HADS-D, $r = 0.47$, $p < 0.001$) was stronger than with anxiety (HADS-A, $r = 0.38$, $p < 0.001$).

For a DT score ≥ 5, ROC analysis yielded a sensitivity of 71.4% and a specificity of 75.3% for detecting moderate or severe psychological distress (HADS ≥ 15, AUC 0.782).

The REPERES-G, collected from a subgroup ($n = 49$), showed high treatment satisfaction with a median score of 132 (min 90, max 163). Especially the "satisfaction with medical aspects of treatment" (REPERES-G medical aspects) showed a moderate correlation with the DT ($r = 0.51$, $p < 0.001$) a strong correlation with anxiety and depression (HADS total, $r = 0.69$, $p < 0.001$).

Conclusion: About three in four patients with musculoskeletal tumors have relevant psychological distress. A visual analogue scale can only be a rough guide for identifying patients in need of psychological support, with a

sensitivity of 71.4 % and a specificity of 75.3 %. A strong relationship between patient and care team was associated with lower patient psychological distress.

Consequently, screening tools cannot replace detailed discussion and personal contact, especially in the treatment of malignant diseases.

1. Introduction

Early psychological intervention for psychosocial distress in cancer patients is a critical domain of quality cancer care [1]. Psychological comorbidities have been shown to be associated with negative effects on treatment, compliance and the clinical outcome [1–4]. Therefore, an early screening for psychosocial distress before the initial treatment is highly recommended [5,6]. Moreover, several guidelines emphasize that patients should be screened at different stages across the trajectory of the illness [7–9]. More than 50 % of the patients report to have psychological distress and about one in three patients has mental disorders. The challenge is to identify those cancer patients who are vulnerable to develop severe mental health issues [7,10,8,11,3,12–15]. Apart from that, the objective physical state of a person cannot be considered as a reliable indication of distress [7,16,17]. In daily clinical practice, there is a need for tools that allow efficient screening without interfering with clinical practice. Consequently, established screening instruments such as the Distress Thermometer (DT) and other non-cancer related instruments to detect anxiety and depression have been used [7,18,19].. Many physicians often expect the patients to mention a problem even though one quarter of the people do not speak about their mental health issues unless they are invited to do so [7,8,20]. The utility of a proactive distress screening is thus underlined. The DT has been widely used in research and has been recommended as a clinical tool to be used to detect psychological distress in cancer patients. It has been validated for more than 20 languages several countries [21]. The most established cut-off of the English version with an optimal sensitivity and specificity for a general cancer population has been reported to be a DT score of 4 [2221]. A validation study for the German version of the DT recommended a cut-off score of 5 with a sensitivity of 0.84 when screening for moderate levels of anxiety or/and depression [19]. While the DT has been evaluated and validated broadly for general cancer populations, there has been no validation for patients with musculo-skeletal tumors [21].

Musculoskeletal tumors, whether primary or secondary, can cause pain and neurological deficits and result in different degrees of loss of function and quality of life [23,8,24]. While physical functional aspects of patients with musculoskeletal tumors have been investigated thoroughly, psychological aspects and the social reintegration after treatment were widely neglected [23,3]. However, it is known that patients with musculoskeletal tumors are vulnerable for psychological distress [11,8].

Hence, the aim of this study was to validate the DT in a cohort of musculoskeletal tumor patients against an established anxiety and depression screener and to further explore associations with treatment satisfaction and health literacy.

2. Materials and Methods

We conducted a monocentric prospective cohort study through a paper-based survey. This study was approved by the local institutional ethics committee (reference 354/20-ek).

2.1. Patients

We enrolled adult patients at the musculoskeletal tumor outpatient clinic at a German University Medical Center from Oct 2020 to Jul 2021. Inclusion criteria were a confirmed diagnosis of at least one either primary or secondary musculoskeletal tumor (including uncertain/benign

tumors during diagnostic work-up), age 18 years or older, and proficiency in German. Exclusion criteria comprised severe physical, cognitive, and/or verbal impairments that interfered with a patient's ability to give informed consent for research.

Patients were screened during their scheduled appointments in the outpatient department and informed consent was obtained. After inclusion, questionnaires for the Distress Thermometer and the Hospital Anxiety and Depression Scale were completed by all patients. A subgroup of patients (n = 49) completed the Health Literacy Survey of the EU (HLS-EU-Q16) and the Patient Satisfaction with Comprehensive Cancer Care (SCCC/REPERES) questionnaire..

Epidemiological data and data on the course of treatment was obtained from the clinical information system for all patients who had completed questionnaires.

The survey included the following instruments in their validated German versions:

2.2. Distress Thermometer (DT)

The NCCN Distress Thermometer is a widely used screening tool developed by Roth et al. to assess psychosocial distress in cancer patients [19,25]. The screening contains a single-item visual analogue scale ranging from 0 ("no distress") to 10 ("extreme distress") to quantify the global level of distress experienced in the past week including the current day.

For general cancer populations, a score of ≥ 5 at the visual analogue scale is recommended as a cut-off for a clinically significant level of distress and a referral scheme to appropriate professional services.

2.3. The Hospital anxiety and depression scale (HADS)

The HADS is a self-report questionnaire designed to identify and quantify symptoms of anxiety and depression in physically ill patients and finds widespread use in various settings beyond the medical setting [26–28]. This instrument consists of two subscales with seven items each measuring anxiety and depression to a total of fourteen items.

A total of eight and more on each subscale indicates in two subscales the presence and severity of anxiety (HADS-A) or depression (HADS-B). Each subscale ranges from mild (8–10) to moderate (11–14) and severe (15–21). The composite score represents the summation score of the corresponding anxiety and depression subsets and the maximum score is 42 with higher scores indicating more distress. The total HADS score combines the scores of the two subscales and ranges from 0 to 42 with mild (0–15) to moderate (15–21) and severe (greater than21) psychological distress.

2.4. European health literacy survey questionnaire (HLS-EU-Q16)

The short version HLS-EU-Q16 of the instrument developed within the framework of the European Health Literacy Survey (HLS-EU) was used to record health literacy [29,30]. The HLS-EU-Q16 captures four dimensions of general health literacy (accessing, understanding, assessing, and applying health information) in the areas of disease prevention, health promotion, and health care.

2.5. Patient satisfaction with Comprehensive cancer care (SCCC) (REPERES)

In a subgroup of all participants, the patient's satisfaction with

medical and psychosocial cancer care was additionally assessed using the 33-item abbreviated German version of the REPERES-60 questionnaire (Patient Satisfaction with Comprehensive Cancer Care (SCCC) REPERES-G) [31–33]. The REPERES-G includes four dimensions: (1) satisfaction with physicians' competence and human qualities, (2) satisfaction with information provided by physicians, (3) satisfaction with access to psychological and psychosocial support, (4) satisfaction with psychological support provided by medical staff. Three additional items were used to measure overall satisfaction with medical and psychosocial care.

2.6. Statistical analysis

All analyses were performed with the Statistical Package for the Social Sciences (SPSS) version 27. Chi Square or Fisher's Exact tests were used to compare frequencies of categorical data. In order to assess the ability of the DT to reflect distress in a cohort of patients with musculoskeletal tumors correctly, Pearson's correlation coefficients (r) were calculated between the DT and subsets and the total score of the HADS. Receiver operating characteristic (ROC) tables were computed to examine the sensitivity and specifity of threshold DT values that would correctly detect patients with relevant anxiety and/or depression (HADS $\geq$ 15) [34]. For all implemented inferential tests, the significance level alpha was set at $p < 0.05$.

3. Results

In total, 141 patients were asked to participate in the survey. Five patients could not speak German, six patients rejected participation, and ten patients agreed to participate but did not complete the questionnaires. Hence, questionnaires of 120 patients (mean age 58 years, range 19–89, SD 18) of whom 50.8 % were female were available for analysis.

Eighty-three participants (69.2 %) lived in a relationship. The highest professional degree was an apprenticeship for 72 respondents (60.0 %), a technical college for 21 (17.5 %) and a university for 22 (18.3 %). Five of the respondents (4.2 %) had no degree. Sixty-one subjects were employed (50.8 %), 54 (45.0 %) were retired, and five (4.2 %) were unemployed.

A malignant tumor had been diagnosed in 61 participants (50.8 %), the remainder had a benign lesion or a tumor of unknown dignity. A metastatic disease was present in 28 participants (23.3 %).

3.1. Validity of the distress Thermometer

Patients reported a mean DT of 5.0 (SD 2.3, range, 0 to 10). Eighty-six patients (71.7 %) had a DT score $\geq$ 5 indicating moderate or severe psychological distress.

The mean total HADS score (scale 0 to 42 points) was 11.7 (SD 7.6, range, 0 to 32) with a HADS score of $\geq$ 15 in 29.2% of patients. The DT correlated moderately with anxiety and/or depression (HADS total, r = 0.48, p < 0.001), while the correlation with depression (HADS-D, r = 0.47, p < 0.001) was stronger than with anxiety (HADS-A, r = 0.38, p < 0.001).

For a DT score $\geq$ 5, the ROC analysis yielded a sensitivity of 71.4% and a specificity of 75.3% for detecting moderate or severe psychological distress (HADS $\geq$ 15, AUC 0.78, Fig. 1).

3.2. Associations with patient satisfaction

The REPERES-G, collected from a subgroup (n = 49), showed high treatment satisfaction with a mean score of 132 (SD 17, range, 90 to 163). Especially the "satisfaction with medical aspects of treatment" (REPERES-G medical aspects) showed a moderate correlation with the DT (r = 0.51, p < 0.001) and a strong correlation with anxiety and depression (HADS total, r = 0.69, p < 0.001). Moderate negative correlations with the DT were observed for "satisfaction with support by
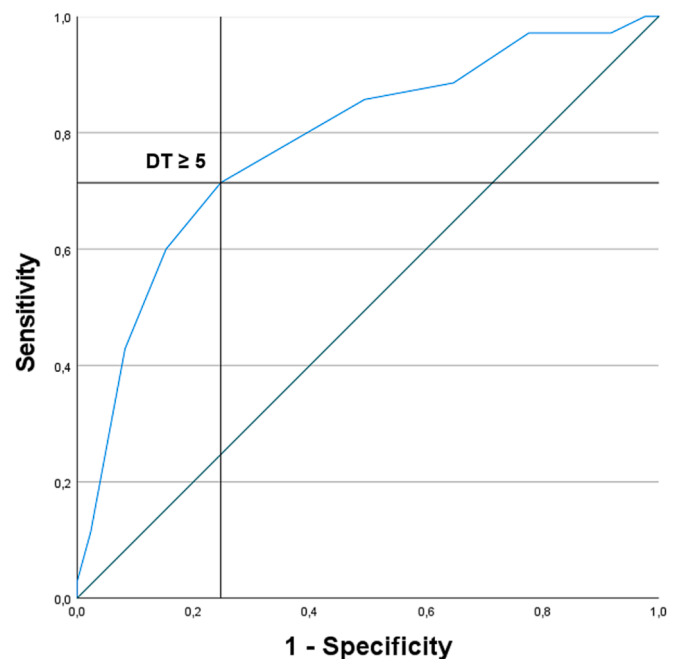

Fig. 1. Receiver-Operating Curve for a DT cut-off of $\geq$ 5.

ward staff" (r = -0.42, p < 0.003) and "general satisfaction" (r = -0.47, p < 0.001).

3.3. Associations with health literacy

The mean HLS-EU-Q16 was 13 (SD 2, range, 0 to 47). There was only a weak correlation between the HLS-EU-Q16 and the DT (r = 0.30, p = 0.047) and a moderate correlation with the total HADS score (r = 0.51, p < 0.001).

4. Discussion

The aim of this study was to validate the Distress Thermometer for the detection of psychosocial distress in musculoskeletal tumor patients and to investigate potential correlations with treatment satisfaction and health literacy.

According to previous studies, more than one in two cancer patients suffer from severe psychological distress [7,10,8,11,3,12–15]. This is consistent with the data of the present study, in which relevant psychological distress (DT $\geq$ 5) was observed in 72 % of the patients.

However, distress levels in different collectives can only be compared if the same definitions and tools are used to detect them [8]. For the validation of the DT we employed the HADS which is a well-established instrument that has also been used to validate other distress screening tools [2,19,7]. Our results demonstrate a moderate correlation between the two scales. For a cut-off of $\geq$ 5, the DT yielded a sensitivity of 71.4% and a specificity of 75.3% for detecting moderate or severe psychological distress (HADS $\geq$ 15). In this study, we observed lower correlations between the HADS and the DT than other studies [7,35,19]. One reason for the mismatch between earlier studies and our results might be that in musculoskeletal tumors bodily pain and reduced body function play a greater role compared to general cancer cohorts.

Consequently, the DT is neither a very sensitive nor a very specific short screening instrument for detecting distress in musculoskeletal tumor patients. Thus, it should not be utilized on its own for standardized detection of severe distress levels in a musculoskeletal tumor outpatient clinic.

However, in this study, a very strong negative correlation was found between patient satisfaction with medical aspects of treatment and

higher degrees of psychological distress. Earlier studies underline that lower satisfaction of care is associated with anxiety and less compliance. Taking into account the uncertainty of the illness and the repeated appointments in a tumor outpatient clinic, the trust in healthcare providers is very important [36].

The results on health literacy of the present study as measured by the HLS-EU-Q16 suggest that there is a moderate correlation between health literacy and the presence of anxiety and depression. These findings support the idea that low health literacy is frequently associated with psychological distress and that cancer patients who have a poor understanding of their disease may experience greater anxiety and be more dissatisfied with their care [37,38]. This is in line with previously published data that showed an influence of the educational background of a patient on the ability to cope with the disease [23].

The limitations of this study include the fact that the HADS and the DT are not cancer related screening tools and consequently, do not specify cancer related problems. In addition, this study investigated a very heterogeneous group of patients regarding tumor entity and screening at variable time points of the disease. Nevertheless, it was important to validate the visual analogue scale as a possible screening tool for psychosocial distress in a realistic situation of daily clinical practice. Patients were screened proactively and at variable time points of the disease as recommended by several guidelines. Especially in the face of limited time and changing doctors in a tumor outpatient clinic, this study demonstrates that identifying patients with psychosocial distress remains to be a challenge. Further studies, which take standardized screening focusing on cancer related issues into account, will need to be performed in order to provide a high quality cancer care. Future studies should also examine the optimal time point in the treatment process to screen for psychosocial distress.

A third limitation is that due to the extent of the questionnaires handed out. Only a subgroup answered REPERES G and HLSQ16. Despite of this, our findings highlight that high treatment satisfaction and health literacy are negatively associated with distress. The results of this study may enhance our understanding of correlations between distress, treatment satisfaction and health literacy as most patients spend a long time at outpatient clinics and with their health care providers.

The findings suggest the following questions to be investigated by for future research: Does knowledge about the treatment and the illness help patients to lower anxiety, increase quality of life and what impact would this have on clinical outcome? How does satisfaction with treatment and health literacy affect clinical outcome? Is there a role for prophylactic active education and would information workshops help patients to lower anxiety?

4.1. Conclusion

About three in four patients with musculoskeletal tumors have relevant psychological distress. A visual analogue scale can only be a rough guide for identifying patients in need of psychological support, with a sensitivity of 71.4 % and a specificity of 75.3 %. A strong relationship between patient and care team was associated with lower patient psychological distress. Consequently, screening tools cannot replace detailed discussion and personal contact, especially in the treatment of malignant diseases.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

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