**Screening for Distress using the Distress Thermometer and the University of Washington Quality of Life in Post-treatment Head & Neck Cancer Survivors**

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**Abstract:**

Objectives: The primary aim was to determine the efficacy of the Distress Thermometer (DT) in screening for anxiety and mood problems against the University of Washington Quality of Life, version 4 (UWQOL). Secondary aims were to evaluate the association between demographic, clinical and health-related QOL variables with significant distress.

Methods: 261 disease-free HNC ambulatory patients attending routine follow up clinics were prospectively recruited. Both DT and UWQOL were completed pre-consultation.

Results: Receiver operating characteristic (ROC) curve analyses of DT score for anxiety dysfunction yielded an area under the curve (AUC) of 0.877, with a sensitivity of 84% (43/51) and specificity of 76% (159/210) for a DT cut-off of ≥4; with a corresponding AUC of 0.825 for mood with sensitivity 78% (28/36) and specificity 71% (159/225). Treatment with radiotherapy and a longer consultation time were associated with significant distress. Significant distress was also reported in two-thirds of those reporting less than “Good” overall QOL. Distress levels were particularly associated with poorer Social-Emotional function, more so than the association seen with poorer Physical function.

Outcomes: DT is a reasonable screening tool for distress in the HNC population. The DT cut-off score ≥4 was effective in identifying those with significant distress. Significant distress is associated in survivors with poorer HRQOL, those who received radiotherapy and patients who have longer consultation times in clinic.

**Keywords:** Distress - Head and Neck Cancer – University of Washington Quality of Life – Distress Thermometer - Screening

**Background**

Cancer-related distress is *‘a multifactorial, unpleasant experience of a psychological,* *social or spiritual nature, that interferes with the ability to cope with cancer treatment, its physical symptoms and its treatment. Distress extends along a continuum from common normal feelings of vulnerability, sadness and fear, to disabling problems, such as true depression, anxiety, panic and feeling isolated or in a spiritual crisis’* 1. Cancer-related distress is common2. It is reported that 35-70% of cancer patients experience distress at some time during their cancer journey 2. Between 20–44% head and neck cancer (HNC) survivors will experience clinically significant depressive or anxiety symptoms at least once during the course of their illness 3,4.

Longitudinal studies report cancer survivors may experience the trajectory of distress differently, and different factors, including demographic, clinical and social parameters, can influence the severity and consequential effects of distress 5. Head and neck cancer (HNC) patients are prone to psychological problems because social interactions and emotional expression depends largely upon the structural and functional integrity of the HN region 6. Those with preexisting psychological morbidity, serious comorbidity, or are socially isolated, are particularly at risk of psychological distress 6. This population demonstrates a high incidence of anxiety immediately post-diagnosis while depression peaks approximately 3 months post-completion of treatment, and levels for both constructs tend to return to pre-treatment levels by 12 months post-treatment completion 7,8. In addition, fear of cancer recurrence (FoR) is the most common concern of disease-free HNC survivors 9,10 and can cause severe psychological morbidity 11. Longitudinal follow-up suggests that screening for mood and anxiety may help identify those with persistent significant FoR due to its close association 12.

Distress impacts negatively on cancer care and outcomes, namely, quality of life (QOL) 13,14, treatment adherence 15, satisfaction with care 16, and survival 17. Distress levels in HNC patients have also been shown to relate negatively with QOL 18 and predicts survival in HNC patients 19. Screening for distress is the first vital step in identifying patients who may be vulnerable to the damaging impact of chronic and/or significant distress 2,5. This sign-posting exercise may also aid professionals in developing with HNC survivors an individualized supportive care plan, incorporating various services including physical rehabilitation 20, social support 6 and psychosocial interventions 21, because cancer-related distress is explicitly tied to a number of common practical, physical, and psychological problems/concerns 5.

The Distress thermometer (DT) was introduced in 1998 as a rapid screening instrument for cancer-related distress 22 and has been validated for various cancer types worldwide 23, including the United Kingdom 24. However, the DT has never been used to determine distress in a HNC cohort. Screening for psychological distress in HNC has been carried using various tools, include the General Health Questionnaire 18,19 and in particular, the Hospital Anxiety Depression Scale (HADS) 7,8,25-28. Mood and Anxiety constructs were incorporated into the University of Washington Quality of Life (UWQOL), a widely used HNC-specific, validated health-related QOL measure 29. The UWQOL is highly correlated with HADS 27 and thus, UWQOL has been used in routine clinical practice as a tool to help screen for a significant problem in these two areas 30.

The primary objective of this study was to screen for distress in post-treatment HNC patients using the DT and to determine an effective DT cut off score for this cohort. The secondary aims were to examine the relationship between significant distress with clinicopathological factors and quality of life.

**Materials and Methods**

This work is part of a wider prospective roll out study on the Patients Concerns Inventory 31 and obtained research ethics approval from the North West Research ethics committee (study reference: 11/H1002/7).

*Subjects and recruitment*

Potential patients were derived from the outpatient clinic patient list of four participating HNC surgery consultants. These were two oral and maxillofacial/HNC surgeons (RJ, JB) and two otolaryngology/HNC surgeons (ST, TJ). The inclusion criteria for patient recruitment were disease-free HNC survivors who had completed primary treatment of at least 6 weeks. The exclusion criteria included HNC patients who had active/recurrent disease, those at the pre-treatment or palliative stage of survivorship, and those unable to speak or read English.

 All eligible patients were sent the study patient information sheet together with their clinic appointment letter 6 weeks before their appointment date. On the day of appointment, eligible patients were approached in the waiting area for recruitment. Informed consent was sought and formalised. Recruitment opened on 15 June 2011 and patients were prospectively recruited consecutively according to the date and time of their clinic attendance. Recruitment closed on 9 January 2013.

*Study design*

Recruited patients completed the DT and UWQOL before their consultation. The consultation was audio-recorded as part of the wider Patient Concerns Inventory study. The digital audio-recording encompassed the entire consultation 31.

*Measures*

University of Washington Quality of Life, version 4 (UWQOL)

The UWQOL comprises 12 domains, scaled from 0 (worst) to 100 (best) according to the hierarchy of response 29. The UWQOL has two subscale composite scoresi.e. ‘Physical function’ and ‘Social-Emotional function’ and a single six-point ‘overall’ QOL measure. ‘Physical function’ is the simple average of the swallowing, chewing, speech, saliva, taste and appearance domain scores whilst ‘Social-Emotional function’ is the simple average of the activity, recreation, pain, mood, anxiety and shoulder domains. In regard to the single item overall QOL scale, respondents were asked to consider not only physical & mental health, but also other factors, such as family, friends, spirituality or personal leisure activities important to their enjoyment of life.

To allow incorporation of UWQOL into routine clinical practice *viz.* screening for dysfunction, a ‘significant problem’ was considered present in a particular UWQOL domain when it fulfills one of the following criteria: (1) scores beyond a cut-off point specified in a domain, (2) (for some domains only) a score adjacent to the cut-off and respondents indicating the particular domain as being important during the previous week 30. For example, a significant problem with Mood is triggered when the UWQOL Mood score was 0 or 25; or selection of Mood as being important in the past 7 days with a Mood score of 50. Furthermore, a significant problem with Anxiety is triggered when UWQOL Anxiety score was 0 or 30.

Distress thermometer (DT)

The DT is a single item self-report measure of distress. This instrument has been used to screen for distress in various types of cancer diagnoses 22-24,32,33. It is scaled from 0 (no distress) to 10 (severe distress) in a thermometer layout to rate the level of distress experienced. A DT score of ≥5 was originally recommended as denoting significant distress necessitating psychosocial referral 34. However, a DT score of ≥4 has been shown to correlate with optimal sensitivity and specificity to the HADS in various cross-cultural studies 13,14,23,32.

*Data analysis*

To examine the relationship between distress and other variables, the Fishers Exact test, Pearson’s chi-squared test or Kruskall-Wallis analysis were applied as appropriate. Statistical significance was regarded as p<0.01. Receiver operating characteristic (ROC) curve analyses were performed to identify a DT cut-off score that effectively detects cases of significant distress defined by the UWQOL screening for dysfunction in anxiety and mood from the UWQOL 30. All statistical analysis was performed using the SPSS version 19.0 (SPSS Inc.).

**Results**

There were 261 patients recruited at 325 clinics and data were analysed for the first clinic at which the PCI was used. Clinico-pathological characteristics of the patients recruited to this study are shown in Table 1. Overall the median (IQR) time from primary surgery (or from primary diagnosis if no surgery) to clinic attendance was 2.2 (0.9-3.8) years, n=256. The median (IQR) length of consultation was 4.9 (3.2-7.4) minutes, n=213.

*Distress levels and identification of the DT cutoff*

The mean DT score overall was 2.9 and the median (IQR) was 2 (0-5) (Table 2). The overall rate of significant distress (defined by a DT cut-off score of ≥4) was 36% (94/261). Thus, by this definition about two-thirds of this cohort at clinic did not report significant distress.

ROCS analysis was performed to identify suitable DT cut-off points for emotional distress as defined as a ‘significant problem’ in the UWQOL mood (14%, 36/261) and anxiety (20%, 51/261) domains. Areas under the ROC curve (AUC) estimate the discriminative accuracy of cut-off scores in relation to a binary criterion, with a range from 1 (perfect discriminative accuracy) to 0.5 (poor discriminative accuracy) 13. The ROC analyses showing the AUC using the DT as a predictor of UWQOL dysfunction are summarised in Table 3 and higher areas under the curve are apparent towards dysfunction in domains within the social-emotional subscale of the UWQOL than for domains within the physical functioning subscale. The highest areas were for anxiety and mood dysfunction (Figure 1), and for these Table 4 shows sensitivity and specificity values for binary cut-offs within the distribution of DT scores.

The ROC analyses offered support for cut-offs at ≥4 or ≥5. DT score yielded an AUC of 0.877 for anxiety dysfunction with a cut-off of ≥4 giving a sensitivity of 84% (43/51), specificity of 76% (159/210), positive predictive value of 46% (43/94) and negative predictive value of 95% (159/167); with a corresponding AUC of 0.825 for mood with sensitivity 78% (28/36), specificity 71% (159/225) positive predictive value of 30% (28/94) and negative predictive value of 95% (159/167).

Defining significant distress by a DT score cut-off of ≥5 gave a distress rate slightly lower at 31% (80/261). In predicting anxiety dysfunction it gave a sensitivity of 78% (40/51), specificity of 81% (170/210), positive predictive value of 50% (40/80) and negative predictive value of 94% (170/181); whilst in predicting mood dysfunction gave a sensitivity of 78% (28/36), specificity 77% (173/225), positive predictive value of 35% (28/80) and negative predictive value of 96% (173/181).

*Relationship between DT score and clinicopathological variables*

The relationship between significant distress (DT score ≥4) and age at consultation, sex, surgical specialty, histology, primary site, tumour stage, treatment, length of consultation and length of follow up were evaluated. Only two variables showed a statistically significant association with significant distress, namely, length of consultation (Mann-Whitney test, p<0.001) and treatment (Chi-square, p=0.01). For consultations lasting under 4 minutes the distress rate was 26% (22/85), between 4 and 8 minutes it was 34% (27/79) and for more than 8 minutes it was 57% (28/49). For patients having had primary surgery alone the rate was 30% (34/114), for surgery with adjuvant RT it was 37% (37/100), and for RT/CT without surgery it was 56% (22/39).

Other variables failed to demonstrate a statistically significant association with significant distress at p<0.01, but age (p=0.04, Mann-Whitney) and overall P-stage (p=0.04, Chi-squared) were borderline associations, with higher distress rates noted for those aged under 55 years (51%, 27/53) and for those with advanced P-stage 4 tumours (48%, 33/77).

*Distress and quality of life*

The DT scores correlated moderately (rs=-0.44) to UWQOL Physical subscale scores but more strongly (rs= -0.65) with the Social-Emotional subscale score. Those scoring under 50 on the Social-Emotional scale were notably distressed (85% 22/26), with the rate decreasing as the score increased – 61% (37/61) for 50-69 scores, 38% (20/52) for 70-79 scores and 12% (15/122) for 80-100 scores. For physical subscale scores under 50 the distress rate was 57% (13/23), with 47% (34/73) for scores 50-69, 53% (21/40) for scores 70-79 and 21% (26/125) for scores 80-100. Spearman correlation was rs=-0.52 with overall QOL and 95% (20/21) of those with ‘very poor’ or ‘poor’ QOL had significant DT distress, 60% (27/45) of those with ‘fair’ QOL, 34% (33/96) of those with ‘good’ QOL and 14% (14/99) of those with ‘very good’ or ‘outstanding’ QOL.

Using the UWQOL dysfunction algorithm, significant dysfunction in anxiety OR mood was reported in 24%, 63/261. In addition, patients with significant problems in areas of Pain, Activity, Recreation, Mood and Anxiety were more likely to report significant distress (Fisher exact test, p ≤ 0.001 in all). The reported importance of Pain, Mood and Anxiety in the past week was also associated with significant distress (p≤0.001).

**Discussion**

This study evaluated the efficaciousness of DT in screening for significant distress in a disease-free, post-treatment HNC survivors attending a routine outpatient clinic. According to NCCN guidelines 34, those with a score of ≥ 5 would require a referral for psychosocial care team, based on the recommendation that this cut off represents the threshold for those who will benefit from psychiatric referral 32. Our study uses the UWQOL algorithm to attempts to provide empirical evidence for this type of clinical judgment in relation to the HNC cohort.

Receiver operating characteristic analysis revealed that both DT cut-off scores ≥4 and ≥5 yielded AUC estimates indicating good overall accuracy relative to UWQOL dysfunction scores for Mood and Anxiety. However, the DT cut-off score ≥4 was found to be more effective in discriminating those with significant emotional distress compared with a ≥5 cut off score. In terms of predicting anxiety dysfunction, in choosing the ≥4 over ≥5 cut-off score, there is a trade off i.e. there is better sensitivity with ≥4 (84% versus 78%) but worse specificity (76% versus 81%). In terms of predicting mood dysfunction, the ≥5 is only slightly more effective as the sensitivity rate is equal to the ≥4 cut off (i.e. 78%) but shows better specificity (77% versus 71%). Table 4 suggests that having a cut-off other than ≥4 or ≥5 reduces sensitivity or specificity quite considerably, and hence, the most optimal cut-off probably lies between 4 or 5. From a purely practical screening perspective of wanting to be inclusive and confident of capturing cases of dysfunction, the clinical choice would be to use ≥4 rather than ≥5. This is may be the reason why both cut-offs have been suggested in the literature. While HADS was not used in this study, our results echo the findings of other studies that have evaluated a DT cut-off score ≥4 relative to HADS in cohorts at a similar plane on the cancer trajectory i.e. post-treatment cancer patients attending outpatient clinics 23,32. Our finding may be related to the strong correlation between UWQOL with HADS 27,30.

Significant distress as determined by DT (cut-off score ≥4) was 36% in this cohort. When using the UWQOL algorithm, the significant mood and/or anxiety dysfunction rate was 24% (63/261), which is similar to that seen in our previous work in different group of post-treatment disease-free HNC, where the reported rate was 26% (116/454) 4. When UWQOL was combined with the Patients Concerns Inventory, a patient-reported tool that aids patients in highlighting their concerns, the proportion of patients with significant mood and anxiety problems/concerns was higher i.e. 44% (89/204). In addition, those with had significant mood and anxiety problems identified by UWQOL alone and the UWQOL-PCI combination showed a higher onward referral rate for psychological support 4. The pick up rate using the UWQOL-PCI combination is nearer to the rate reported with DT with cut-off score ≥4. Based on this observation, we extrapolate that the DT cut-off score ≥4 may be able to identify most of HNC patients with significant distress.

In this study, only two clinical-pathological variables, namely, treatment received and length of consultation, were associated with significant distress. In this cohort, RT as a single modality or within a multimodality approach is associated with significant distress. It is known that HNC patients experience increasing symptoms of depression during RT 27. Depressive symptoms persist post-radiation 3,8 and while there is slight improvement with time, depression levels remain worse than at pre-treatment 35. This is also reported by those irradiated post-surgery 3,36. In contrast, anxiety is less pronounced in HNC patients during RT, which improves after completion of RT 8. RT-related distress is purportedly related to symptoms burden from side-effects of RT 8 particularly pain and fatigue in the acute stage, and xerostomia, trismus and osteoradionecrosis in the long-term. This could account for the higher referral rates for psychological support in irradiated HNC patients compared with other cancer types receiving RT 37. It is surprising that the tumour stage did not directly relate to distress because tumours with larger dimensions tend to cause more dysfunction due to the extent and combination of treatment rendered. This may be due to the manner by which the analysis was undertaken.

A longer consultation time was associated with significant distress in this study. Consultation comprises of proportional time dedicated to HN examination, inspection of surgical wounds/dressing and patient-doctor discussions on a range of topics that may be related or otherwise to HNC. Any concerning issue(s) could result in an increase in the overall consultation time, e.g. through having extensive physical examinations and/or longer discussions. This may be relevant as the number and severity of cancer patients’ concerns are associated with the development of distress 38. Distress during routine oncology consultations is frequently associated with FoR 11, which is the most common concern in HNC clinic visits 9,10,12. Patients find physical examination and direct reference to issues surrounding cancer recurrence during clinic appointment discussions reassuring 39 and this may account for longer consultations. Our previous work did not reveal any relationship between the number and type of patient concerns/issues with significant mood and/or anxiety problems 4, but this is the subject of further data analysis in this current cohort (in press). In a study of adjuncts in facilitating oncology consultations e.g. prompt sheet for patients, higher levels of distress were related to longer consultation times and this was attributed to the contents of the prompt sheet, which include prompts to difficult questions, e.g. prognosis 40. Associations between younger age, gender, performance status, and tumour characteristics with significant distress in HNC patients evident elsewhere 7,25,26 were not noted in our study.

The association between HRQOL with significant distress was evaluated. In our cohort, significant distress was experienced in two-thirds reporting less than “Good” overall QOL, suggesting an association between significant distress and poorer HRQOL, which is not unexpected, and in accordance to previous work 7,8,25. Distress levels were particularly associated with poorer Social-Emotional function, more so than the association seen with poorer Physical function. This may be related to the additional finding of patients with significant problems in the individual areas of Pain, Activity, Recreation, Mood and Anxiety (i.e. components of the Social-Emotional function subscale) were more likely to report significant distress. Physical functioning showed moderate correlation to significant distress. There is an existing body of literature that supports the notion that both psychosocial and physical correlates contribute towards psychological distress and impacts upon HRQOL 20.

This study may be limited by not including a validated screening tool for anxiety and depression, such as the HADS. The addition of a psychological screening tool may speculatively enhance the overall accuracy, including the sensitivity and specificity of the DT cut-off score identified for a HNC cohort. Another limitation relates to the sample lacking diversity, where patients outside the defined cancer trajectory were excluded i.e. pre-treatment, active treatment and palliative stages, and this may influence generalizability of the DT cut-off score identified. Furthermore, the DT cut off score of ≥4 was not cross-validated in a second sample, which may provide additional assurances particularly as a validated psychological screening tool was not used. This study did not evaluate other recognised factors related to distress, including performance status, comorbidity and other sociodemographic data e.g. education and employment. This current paper is unable to comment on the beneficial outcomes of distress screening, which is a subject of another publication (in press).

**Conclusions**

DT is a reasonable screening tool for distress in the HNC population. The DT cut-off score ≥4 was effective in identifying those with significant distress. Significant distress is associated in survivors with poorer HRQOL, those who received radiotherapy and patients who have longer consultation times in clinic.

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**Table 1: Clinicopathological characteristics of 261 patients at first study clinic**

|  |  |  |
| --- | --- | --- |
|  |  | All patients(n=261) |
| Sex | Male | 68% (175) |
|  | Female | 32% (83) |
|  | Not known | 1% (3) |
| Age | Mean (SD) | 63.0 (12.4) |
|  | Median (IQR) | 63 (57-71) |
|  | <55 | 20% (53) |
|  | 55-64 | 34% (89) |
|  | 65-74 | 30% (77) |
|  | 75+ | 14% (37) |
|  | Not known | 2% (5) |
| Specialty | MFU | 52% (136) |
|  | ENT | 48% (124) |
|  | Not known | 0.4% (1) |
| Tumour site | Oral | 34% (90) |
|  | Oro-pharyngeal | 21% (55) |
|  | Laryngeal | 20% (52) |
|  | Other | 25% (64) |
| Histology | SCC | 83% (217) |
|  | Not SCC | 16% (43) |
|  | Not known | 0.4% (1) |
| Overall  | 1 | 28% (73) |
| pTNM stage | 2 | 25% (66) |
|  | 3 | 11% (29) |
|  | 4 | 20% (52) |
|  | Not known | 16% (41) |
| Primary | Surgery only | 44% (114) |
| Treatment | Surgery + RT/CRT | 38% (100) |
|  | RT/CRT only | 15% (39) |
|  | Not known | 3% (8) |
| Free-flap(214 surgery) | Surgery without FF | 70% (149) |
| Surgery with FF | 29% (63) |
|  | Not known | 1% (2) |

**Table 2: Level of reported distress at first study clinic prior to consultation**

|  |  |
| --- | --- |
| DT score | All clinics(n=261) |
| 0 No distress | 32% (84) |
| 1 | 10% (27) |
| 2 | 12% (31)  |
| 3 | 10% (25) |
| 4 | 5% (14) |
| 5 | 9% (23) |
| 6 | 5% (14) |
| 7 | 8% (20) |
| 8 | 5% (12) |
| 9 | 1% (2) |
| 10 Extreme distress | 3% (9) |
| Mean | 2.9 |
| Median (IQR) | 2 (0-5) |

**Table 3: Area under the Receiver Operative Curve (AUC) for DT score predicting a significant problem (dysfunction) in UWQOL domains**

|  |  |  |  |
| --- | --- | --- | --- |
| Domains in the Physical Function subscale of the UWQOL | Area under Curve | Domains in the Social-Emotional subscale of the UWQOL | Area under curve |
| Appearance | .628 | Pain | .763 |
| Swallowing | .668 | Activity | .755 |
| Chewing | .618 | Recreation | .795 |
| Speech | .691 | Shoulder | .674 |
| Taste | .626 | Mood | .825 |
| Saliva | .662 | Anxiety | .877 |

The AUC can be used as a summary measure of how well the DT predicts a binary outcome i.e. having a significant problem as derived from the UWQOL algorithm

**Table 4: Sensitivity and specificity values for binary cut-offs within the distribution of DT scores in regard to UWQOL anxiety and mood dysfunction.**

|  |  |  |
| --- | --- | --- |
|  | Anxiety | Mood |
| Cut-off DT score | %Sensitivity | %Specificity | %Sensitivity | %Specificity |
| ≥1 | 100 | 40 | 97 | 37 |
| ≥2 | 96 | 52 | 92 | 48 |
| ≥3 | 88 | 65 | 86 | 61 |
| ≥4 | 84 | 76 | 78 | 71 |
| ≥5 | 78 | 81 | 78 | 77 |
| ≥6 | 65 | 89 | 64 | 85 |
| ≥7 | 53 | 92 | 50 | 89 |
| ≥8 | 35 | 98 | 33 | 95 |
| ≥9 | 18 | 99 | 14 | 97 |

**Figure 1: ROC comparing DT score with UWQOL anxiety and mood dysfunction**

|  |  |
| --- | --- |
| DT>=4 cut-off | DT>=4 cut-off |
| AUC with Anxiety | AUC with Mood |