**Using the Patients Concerns Inventory for Distress Screening in Post-treatment Head and Neck Cancer Survivors**

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**Summary**

**Purpose:** Cancer patients can experience significant distress during their cancer trajectory, which impacts upon clinical outcomes and quality of life. Screening for distress using holistic assessments can help identify and address unmet concerns/needs. The purpose of this study was to evaluate the relationship between concerns and distress, and the impact of distress on clinic outcomes in post-treatment head and neck cancer patients.

**Methods:** 170 patients attending routine follow-up clinics were prospectively recruited. All completed the Patient Concerns Inventory (PCI) and the Distress thermometer (DT) at preconsultation.

**Results:** The rate of significant distress (i.e. DT cut-off score ≥4) was 36% (62/170). Significantly distressed patients selected more items overall than patients without distress (mean, median (QR) of 5.40, 5 (2-8) Vs 2.61, 2 (0-4), p<0.001).  Significant distress was most strongly associated with Physical and Functional well-being (p<0.001) and Psychological and Emotional well-being domains (p=0.001). On balance, there was very little difference noted between cut-off points of either ≥4 or ≥ 5 PCI items of concern selected. Both cut-off points demonstrated an acceptable level of sensitivity, specificity and predictive values for significant distress. Consultations were longer with increasing numbers of concerns.

**Conclusions:** Just over one-third of patients are significantly distressed. They were more likely to express a higher number of concerns. A cut-off score ≥4 or ≥ 5 PCI items selected can identify those at risk of significant distress. Concerns causing significant distress were related to emotional/psychological issues and physical function.

**Keywords: Distress - Head and Neck - Cancer – Patient Concerns Inventory**

**Introduction**

Distress is commonly experienced during the cancer trajectory and significantly impacts upon cancer care and its outcomes, justifying calls for its screening 1. Screening for distress is regarded as the primary step in managing cancer-related distress. This process involves identifying contributing causes, ranging from common practical, physical, and psychological problems/concerns by way of holistic assessments 1,2; and developing individualised supportive care plan to meet these issues. It is suggested that the number and severity of cancer patients’ concerns is associated with development of distress 3,4.

There is an accumulating body of work surrounding patient’s concerns in the head and neck cancer (HNC) population based on the Patients Concerns Inventory (PCI). The PCI is a holistic tool that helps HNC patients disclose items of concern during routine clinical consultations, and also assists patients in indicating professionals with whom they wish to see or be referred to 5. The PCI has been successfully rolled out as a sign-posting tool for supportive care across a regional HNC network in the United Kingdom (UK).

There is a wide range of reported HNC patient concerns 5. Preliminary analysis of this dataset identified the most common patient concerns were fear of recurrence (FoR, 37%), dental health/teeth (27%), chewing (24%), pain in head/neck (20%), fatigue/tiredness (19%), saliva (18%) and swallowing (18%) 5. When the PCI is used in conjunction with other measures, it is possible to identify individuals with significant problems i.e. requiring attention/support in specific areas. For example, those with significant problems from FoR can be identified when the PCI is used in conjunction with the FoR questionnaire 6,7. Also, patients with significant problems in areas of mood and anxiety 8, pain 9, appearance 10, and speech and swallowing 11 can be identified when the PCI is used in conjunction with the University of Washington Quality of Life version 4 (UWQOL).

Different factors related the expression of specific concerns. For example, predictors of those experiencing significant FoR concerns over time (35%) were related to patient-related characteristics (i.e. female gender, those experiencing anxiety and mood disorders) rather than clinicopathological characteristics7. On the other hand, clinicopathological factors were important predictors for those citing pain concerns with significant problems (i.e. received radiotherapy (RT), age < 65 years) 9 and in those citing appearance concerns with significant appearance issues (i.e. oropharyngeal tumours, large primary tumours, and age < 65 years) 10. However, the relationship between patient concerns and distress in HNC has n been explored.

The Distress thermometer (DT) is a rapid, validated screening instrument for cancer-related distress for patients with various cancer types in America and the UK 12. However, there was paucity in the literature regarding patient concerns related to distress and the use of DT in distress screening in HNC population. A DT score of ≥5 was originally recommended as denoting significant distress necessitating psychosocial referral 13 but a DT score of ≥4 has been shown to correlate with optimal sensitivity and specificity to the Hospital Anxiety Depression Scale (HADS) in various cross cultural studies in identifying significant distress 14,15,16. Recently, we found that a DT cut-off score of ≥4 was effective in in screening for significant anxiety and mood problems against the UWQOL in disease-free, post-treatment HNC survivors attending out-patient clinics 18, where just over one-third of HNC patients (36%, 94/261) reported significant distress.

The primary objective of this study was to determine the relationship between distress and patient concerns in a cohort of disease-free, post-treatment HNC patients attending routine follow-up. A specific objective was to evaluate the relationship between the number of concerns with significant distress, so as to identify suitable cut-off point based on the number of items selected on the PCI that could be used as a simple indicator for clinicians in risk assessing significant distress in clinic. The secondary aims were to determine the significance of distress on outcomes of clinic consultations in relation to patient’s concerns.

**Methods**

This study obtained research ethics approval from the North West Research ethics committee (study reference: 11/H1002/7) and was conducted in two HNC outpatient clinics within the Merseyside region.

*Subjects*

Study participants comprised surgeons and patients. Four consultant surgeons comprising two Oral & Maxillofacial surgeons and two Otolaryngology, Head and Neck surgeons, without prior experience of using the PCI were invited to participate in this study and formed a convenience sample. The inclusion criteria for patient recruitment were disease-free HNC survivors who had completed primary treatment of at least 6 weeks and had not used the PCI before. The exclusion criteria included HNC patients who were at pre-treatment or palliative stage of survivorship. In addition, patients who were unable to speak or read English were excluded.

*Measures*

Distress thermometer (DT)

The DT is a single item self-report measure of distress. This instrument is scaled from 0 (no distress) to 10 (severe distress) in a thermometer layout to rate the level of distress experienced. A DT cut-off score of ≥4 correlates with optimal sensitivity and specificity to the HADS in various cross cultural studies 14-16, and is effective in identifying significant anxiety and mood problems with good sensitivity and specificity to the UWQOL in HNC 18.

Patient Concerns Inventory (PCI)

The PCI is a checklist comprising 57 items of patient concern and 18 professionals tiled alphabetically 19. These items have been grouped into 5 domains: (A) Physical and Functional well-being (29 items); (B) Psychological and Emotional well-being/Spiritual (14 items); (C) Social care/Social well-being (9 items); (D) Treatment-related (4 items) and (E) Other (1 items) 20. The PCI asks respondents to indicate items from the checklist they were concerned about and wanted to discuss with the doctor during their consultation. Patients were also asked to indicate professionals from the checklist they would like to speak or be referred to.

*Study design*

This work is part of a wider prospective project evaluating the PCI intervention set up into three study blocks organised sequentially. In Block 1, patients did not complete the PCI before their consultation, representing usual practice and the control group. In Block 2, patients completed the PCI at the pre-consultation stage but the PCI was withheld from clinicians during consultation, representing the ‘control in attention’ group. In Block 3, patients completed the PCI at the pre-consultation stage, the completed PCI was passed on to the clinicians and was available for use during the consultation, representing the intervention group. For the purpose of this study only patients from Blocks 2 and 3 were selected, and the PCI data acquired was derived from the clinic they had first experienced using the PCI.

All recruited patients also completed DT at pre-consultation. Questionnaires were administered in a paper format. The length of consultation was determined from the start to the end of consultation, which was audio-recorded and subsequently transcribed. Thematic content analyses of the audio-recorded transcriptions were carried out by two assessors (NG, BR) based on a thematic framework approach19. Clinic outcomes were classified as medical (e.g. placement on surgical waiting list to aid rehabilitation, institution of symptomatic or supportive medical treatment, request for investigations, and onward referrals) or non-medical actions (e.g. provide information, advice on lifestyle, strategies for coping, and reassurance).

*Data analysis*

To examine the relationship between distress and other variables, Fishers Exact test, Pearson’s chi-squared test or Mann-Whitney analysis were applied as appropriate. Statistical significance was regarded as p≤0.01. All statistical analysis was performed using SPSS version 19.0 (SPSS Inc.).

**Results**

One-hundred and seventy patients (n=170) were recruited at first attendance at clinics within study Blocks 2 and 3 during which they first used the PCI. Clinico-pathological characteristics of these patients 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 (1.2-3.9) years, n=167. The median (IQR) length of consultation was 5.2 (3.2-7.9) minutes, n=141.

*Distress and patient concerns*

The mean DT score overall was 2.9 and the median (IQR) was 2 (0-5). The overall rate of significant distress (i.e. DT cut-off score of ≥4) was 36% (62/170). Thus, about two-thirds (64%, 108/170) of this cohort at clinic did not report significant distress.

Overall, the number of PCI items selected ranged from 0-18, mean 3.63, median (IQR) 2 (1-5). Patients with significant distress selected more items overall than patients without distress (mean, median (QR) of 5.40, 5 (2-8) versus 2.61, 2 (0-4), Mann-Whitney test p<0.001). More specifically, they selected more items from within the Physical and Functional well-being domain (mean 3.87 versus 1.96) and the Psychological and Emotional well-being domain (1.16 versus 0.46) than from the Social care/Social well-being domain (0.21 versus 0.10) and Treatment-related domain (0.16 versus 0.08). The association between PCI items and significant distress is also summarised in Table 2. There were trends within each domain for the likelihood of significant distress to increase with the number of items selected and for this to be compounded within the total score. In stepwise logistic regression to predict significant distress using the category variables within Table 2, the total number of items was the only variable selected (at p<0.001) in regression modeling with p<0.01 inclusion criteria. Three distinct predictive groups were apparent: 21% of patients selecting zero items - 9% (3/35) distressed, 47% selecting 1-4 items - 30% (24/80) distressed, and 32% selecting 5 or more items - 64% (35/55) distressed. Possible cut-offs in the number of PCI items selected in relation to significant distress are explored in Table 3. Specific PCI items associated with significant distress are shown in Table 4.

*Distress and patient concerns and length of consultation*

The median (IQR) number of items actually discussed in the audiorecorded consultations was 3 (2-5) items, n=141. When patients were distressed and three or fewer items were discussed (19 patients), the median (IQR) length of consultation was 4.2 (3.1-6.0) minutes; when four or more items were discussed (33 patients), the median (IQR) consultation length was 8.4 (5.5-12.1) minutes (Mann-Whitney test, p<0.001). In the absence of distress and three or fewer items were discussed (63 patients), the median (IQR) length of consultation was 3.3 (2.6-6.2) minutes; when four or more items were discussed (26 patients) the median (IQR) consultation length was 6.4 (4.3-8.9) minutes (Mann-Whitney test, p<0.001).

*Distress and perceived need for services*

Overall, the number of professionals selected ranged from 0-4, mean 0.38, median (IQR) 0 (0-1), n=170, with a mean 0.53 selected in those with significant distress and a mean 0.30 without significant distress. No strong associations were found with type of professional selected, though it was noted that 52% (11/21) of those wanting to see the surgeon were distressed, 83% (5/6) of those wanting to see the physiotherapist, and all those wanting to see either a psychologist (2/2) or Emotional Support therapist (2/2).

The number of medical actions taken based on audiotaped consultations (n=141) ranged from 1 to 4, and the percentage with 2 or more actions was 52% (27/52) for those with significant distress and 29% (26/89) without distress (Fishers exact test, p=0.01). In regard to non-medical actions (range 2-4), the percentage with 3 or more actions was 37% (19/52) for those with significant distress and 21% (19/89) without distress (Fishers exact test, p=0.18).

**Discussion**

This seminal work evaluated the relationship between patient concerns and distress in post-treatment HNC survivors using PCI. We found a very strong association between level of distress and number of reported concerns. Distress levels were associated with the number of items of concern selected, suggesting that the number of PCI items selected could potentially be a surrogate marker of significant distress. Concerns relating to the Psychological and Emotional well-being and the Physical and Functional well-being domains were related to significant distress. The study also demonstrated that experiencing significant distress and having numerous concerns impacts upon the length of consultations and the outcomes of these consultations. Furthermore, the study findings also suggest that when the PCI is used as a single tool, it can potentially undertake multiple tasks simultaneously i.e. enable patients to voice their concerns, identify those at risk of significant distress, sign-post supportive services required by patients and may facilitate the running of outpatient clinics by indicating which patients may require longer appointments based on their profile of concerns.

The study design allowed a prospective, multicenter recruitment of a cohort representing the breadth of HNC subsites attending routine follow-up clinics run by multiple clinicians of different specialities. The data acquired was cross-sectional and this must be considered in relation to the nature of distress, which can be experienced at anytime during the cancer journey. Furthermore, patient concerns also vary at different time-points along the cancer journey 2. The degree of concern expressed may fluctuate and could contribute differently toward the overall experience of cancer-related distress. We have not specifically attempted to quantify the degree of concern per item selected other than establishing the presence of a significant problem for the item of concern as described previously 5-11.

The majority of patients in this cohort did not experience significant distress (64%, 108/170). Patients with significant distress selected more items overall than patients without distress (mean, median (QR) of 5.40, 5 (2-8) *versus* 2.61, 2 (0-4); Mann-Whitney test, p<0.001). This corresponds to other studies 3,4, where patient concerns were related with the development of distress. The potential relationship between the number of concerns with the likelihood of experiencing significant distress was further evaluated, where it was possible to suggest a cut-off point indicating significant distress with a reasonable degree of sensitivity and specificity. On balance, cut-off points of either ≥4 or ≥5 items of concern selected on the PCI demonstrated an acceptable level of sensitivity, specificity and predictive values (Table 3) for likelihood of experiencing significant distress. From a clinical perspective, using either ≥4 or ≥5 cut-off score can help guide clinicians in risk assessing patients for significant distress, who may benefit from more in depth evaluation and intervention, at pre-consultation.

Those experiencing significant distress were more likely to select items from the Physical and Functional well-being domain (p<0.001) and the Psychological and Emotional well-being domain (p=0.001). This finding demonstrates that emotional distress is not the only significant contributing factor in cancer-related distress in a HNC population predominantly treated with surgery (84%, 142/170). Severe distress, in particular physical distress related to oral cavity dysfunction, has been reported in another HNC cohort treated by ablative surgery and immediate reconstruction 24. Furthermore, the use of RT 18,25 and chemoRT 26 are also strongly associated with significant distress in this population. HNC survivors struggling to cope with the after-effects of HNC treatment are likely to express significant distress and require physical support more than any other cancer types 24,26. Addressing significant distress related to physical concerns can be initiated in clinic. This includes both non-medical (e.g. education, advice, reassurances) and medical actions (e.g. investigations, surgery, medications, referrals). Treatment-related domain was not associated with significant distress (p=0.3). It is possible that disease-free, post-treatment HNC patients were less likely to be significantly distressed about these issues following treatment completion. Comparisons with other studies are not possible due to methodological differences in assessing concerns 14,17.

When individual PCI items of concern were evaluated, Anxiety (p=0.005), Depression (p=0.004), Mood (p=0.01), Pain in head/neck (p=0.002), Sleeping (p=0.007), Fatigue (p=0.001), Swallowing (p<0.001) and Bowel habit (p=0.01) were related to significant distress. Apart from bowel habit, the other concerns associated with significant distress in this study have been consistently been reported by HNC patients previously 5,8,11. It is recognised that Anxiety, Mood and Depression are essential components of, and possible overlapping elements of emotional distress in cancer 27,28. Post-treatment dysphagia is related to weight loss, progressive reduction in swallowing function, narrowing range of oral dietary intake and reliance on gastrostomy tube feeding 29, and these confer a global impact on the long-term day-to-day functioning and QOL 30. Altered bowel function is related to distress in colorectal, urological and gynaecological cancer survivors but this has never been reported previously in HNC cohorts. This finding may be related to complications of opiate analgesia use, alterations to bowel function due to full reliance on enteral feeding and also secondary to hormonal imbalances in a subgroup of thyroid cancers included within this study cohort. Pain is highly correlated to significant distress in HNC patients throughout the survivorship trajectory 25,31. Cancer-related fatigue is a common problem in cancer survivors 32,33 and is linked to emotional reactivity 34,35. Like pain, sleep disturbances and insomnia can occur throughout the survivorship trajectory in HNC survivors 36,37. While individual symptom/concern was related to significant distress in its own right, there is increasing interest in the prevalence of symptoms that frequently co-occur in symptom clusters with distress. For example, sleep disturbances and insomnia occur commonly with other frequently reported side effects of cancer and/or its treatment, namely pain, fatigue, depression and distress 38,39. It is postulated that the clustering of co-occurring symptoms might be related to underlying inflammatory processes common to these concerns 39.

Overall, the number of professionals selected ranged from 0-4, mean 0.38, median (IQR) 0 (0-1), n=170. From the patent’s perspectives, the attending doctor in clinic is often seen as the main clinician managing their cancer care. Thus, it is unsurprising that patients have indicated this professional as the one they would like to see or meet during their appointment, particularly those experiencing significant distress (52%, 11/21). Furthermore, those who were significantly distressed were more likely to select other professionals compared with those not experiencing significant distress (mean 0.53 vs 0.30). In this scenario, perhaps the attending clinician needs to be more proactive in suggesting onward referral or having direct access to the other professionals’ support in clinic. However, it remains unclear why so few additional HNC multidisciplinary personnel are ticked generally on the PCI and this is a subject of future research.

Those significantly distressed with larger numbers of concerns were more likely to have had longer consultations compared with patients not reporting significant distress with fewer concerns. Apart from increasing the length of consultation, significant distress impacts upon the individual management of these patients. Overall, those with significant distress were more likely to receive both medical and non-medical actions related to their consultation compared to those without distress. While this finding is unsurprising, it places huge demand upon resources and outpatient clinic management. A different approach may be required to meet the concerns of significantly distressed patients in clinics where the PCI is used. Suggestions include asking patients to prioritise their list of concerns for discussion during clinic, referral to the most appropriate professional who may be present at the clinic or at another appointment and self-referral through a web-based PCI application. Future work should focus on the impact of PCI-directed pathways in managing distress.

**Conclusions**

Significant distress is experienced in just over one-third of post-treatment HNC patients attending clinic. The PCI has the potential to be a risk assessment tool for significant distress. Using the PCI with a cut-off point ≥ 4 or ≥5 of items selected, it was possible to identify those at risk of significant distress. The concerns of patients with significant distress were related to Psychological and Emotional/Spiritual well-being, and to Physical and Functional well-being. Treatment that maximises functional outcomes without compromising cure should be considered at the outset to address this upfront. A shift of emphasis toward supportive rehabilitation is paramount in the post-treatment period, where managing physical and psychological concerns with close involvement of other personnel within a multidisciplinary team is required. Addressing concerns and distress can result in longer consultations and a higher number of both medical and non-medical actions. Further work is required in understanding the impact of distress screening and PCI-directed pathways in the management of patient concerns.

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**Table 1: Clinicopathological characteristics of the study sample**

|  |  |  |
| --- | --- | --- |
|  |  | All patients(n=170) |
| Gender | Male | 66% (113) |
|  | Female | 33% (56) |
|  | Not known | 0.6% (1) |
| Age | Mean (SD) | 64.2 (11.4) |
|  | Median (IQR) | 64 (58-73) |
|  | <55 | 16% (27) |
|  | 55-64 | 36% (62) |
|  | 65-74 | 30% (51) |
|  | 75+ | 15% (26) |
|  | Not known | 2% (4) |
| Specialty | MFU | 53% (90) |
|  | ENT | 46% (79) |
|  | Not known | 0.6% (1) |
| Tumour site | Oral | 37% (63) |
|  | Oro-pharyngeal | 21% (35) |
|  | Laryngeal | 21% (36) |
|  | Other | 21% (36) |
| Histology | SCC | 84% (143) |
|  | Not SCC | 15% (26) |
|  | Not known | 0.6% (1) |
| Overall  | 1 | 29% (50) |
| P stage | 2 | 18% (31) |
|  | 3 | 11% (18) |
|  | 4 | 29% (50) |
|  | Not known | 12% (21) |
| Primary | Surgery only | 46% (78) |
| Treatment | Surgery + RT/CRT | 38% (64) |
|  | RT/CRT only | 14% (23) |
|  | Not known | 3% (5) |
| Free-flap(142 with surgery) | Surgery without FF | 72% (102) |
| Surgery with FF | 27% (38) |
| Not known | 1% (2) |

**Abbreviation**: MFU, maxillofacial unit; ENT, otorhinolaryngology; SCC, squamous cell carcinoma; RT, radiotherapy; CRT, chemoradiotherapy; FF, free flap

**Table 2. Number of PCI items selected and significant distress (DT≥4)**

|  |  |  |
| --- | --- | --- |
|  | Significant distress (DT≥4) |  |
|  | % | n | P value\* |
| Physical & functional well-being |  |  |  |
| 0 | 20% | 11/56 |  |
| 1-2 | 32% | 16/50 |  |
| 3-4 | 42% | 13/31 | <0.001 |
| 5-9 | 71% | 17/24 |  |
| ≥10 (range 10-15) | 56% | 5/9 |  |
| Treatment related  |  |  |  |
| 0 | 35% | 53/152 | 0.30 |
| ≥1 (range 1-2) | 50% | 9/18 |
| Social care & social well-being |  |  |  |
| 0 | 33% | 50/150 | 0.03 |
| ≥1 (range 1-3) | 60% | 12/20 |
| Psychological, emotional & spiritual wellbeing |  |
| 0 | 28% | 28/100 |  |
| 1-2 | 42% | 24/57 | 0.001 |
| ≥3 (range 3-6) | 77% | 10/13 |  |
| Total number of items |  |  |  |
| 0 | 9% | 3/35 |  |
| 1-2 | 30% | 17/56 |  |
| 3-4 | 29% | 7/24 | <0.001 |
| 5-9 | 61% | 25/41 |  |
| ≥10 (range 10-18) | 71% | 10/14 |  |
| Health professionals |  |  |  |
| 0 | 31% | 37/121 | 0.01 |
| ≥1 (range 1-4) | 51% | 25/49 |

\*chi-square test (physical & functional, psychological emotional & spiritual well-being, total number), otherwise Fisher's exact test.

**Table 3. Possible cut-offs in the number of PCI items in relation to significant distress**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Number of total PCI items as cut-off | Sensitivity | Specificity | Positive Predictive Value | Negative Predictive Value |
| ≥1 | 95% (59/62) | 30% (32/108) | 44% (59/135) | 91% (32/35) |
| ≥2 | 82% (51/62) | 49% (53/108) | 48% (51/106) | 83% (53/64) |
| ≥3 | 68% (42/62) | 66% (71/108) | 53% (42/79) | 78% (71/91) |
| ≥4 | 61% (38/62) | 72% (78/108) | 56% (38/68) | 76% (78/102) |
| ≥5 | 56% (35/62) | 81% (88/108) | 64% (35/55) | 77% (88/115) |
| ≥6 | 42% (26/62) | 88% (95/108) | 67% (26/39) | 73% (95/131) |
| ≥7 | 34% (21/62) | 90% (97/108) | 66% (21/32) | 70% (97/138) |

**Table 4. Specific PCI items associated with significant DT distress**

|  |  |  |  |
| --- | --- | --- | --- |
|  | PCI item selected%DTscore≥4 | PCI item not selected%DTscore≥4 | P value\* |
| PCI item |
| Anxiety | 77 | 10/13 | 33 | 52/157 | 0.005 |
| Bowel | 78 | 7/9 | 34 | 55/161 | 0.01 |
| Depression | 88 | 7/8 | 34 | 55/162 | 0.004 |
| Fatigue | 62 | 21/34 | 30 | 41/136 | 0.001 |
| Mood | 78 | 7/9 | 34 | 55/161 | 0.01 |
| Pain in head/neck | 65 | 17/26 | 31 | 45/144 | 0.002 |
| Sleeping | 65 | 13/20 | 33 | 49/150 | 0.007 |
| Swallowing | 67 | 20/30 | 30 | 42/140 | <0.001 |

\*Fishers exact test