Title: Insomnia, Depression and Anxiety in Patients Urgently Referred with Suspicion of Head and Neck Cancer.

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Abstract

Objective

To determine differences in insomnia, depression, and anxiety between ENT patients with benign and malignant conditions prior to and after an Urgent Suspicion of Cancer (USOC) appointment.

Methods

USOC outpatients completed three psychometric questionnaires prior to their appointment and 2-4 weeks post-diagnosis.

Results

There was no significant difference in questionnaire scores between malignant and benign patients prior to the appointment ($p>0.05$ for all questionnaires). In benign patients, there was significant improvement in scores for all questionnaires ($p<0.01$) and in malignant patients there was significant worsening of scores for all questionnaires ($p<0.01$) at follow up.

Conclusion

Prior to appointments, patients with benign and malignant conditions experience similar levels of insomnia, depression and anxiety. Following diagnosis, cancer patients have significantly poorer scores indicating worsening of these symptoms. In patients with benign diagnoses, all questionnaire scores improved, indicating resolution of their symptoms and possible association between the appointment and their baseline scores.

Keywords: Diagnosis; Health Planning Guidelines; Oral Pathology; Psychology; Sleep.

Introduction

Patients presenting in Scotland's primary care with 'red flag symptoms' of head and neck cancer are referred urgently via the 'Urgent Suspicion of Cancer' (USOC) pathway. The aim of this pathway is to be seen by a specialist at the otolaryngology outpatient clinic within two weeks. The Scottish Referral Guidelines for Suspected Head and Neck Cancer detail these "red flag symptoms". [1]

The USOC and two-week referral pathway has been shown to be ineffective in identifying significant rates of head and neck cancer. [2,3] The proportion of patients attending the otolaryngology outpatient clinic with red flag symptoms of head and neck cancer who go on to receive a diagnosis of head and neck cancer has been shown to be as low as 3% in Glasgow, with many patients being reassured and discharged after one visit with no forms of investigation. [4]

The prevalence of insomnia disorder in patients diagnosed with a head and neck cancer is high before, during and after treatment. [5] It is well documented that those suffering from insomnia are at increased risk of depression and anxiety. [6,7] Both depression and anxiety have been demonstrated to be prevalent in head and neck cancer patients from the time of diagnosis well into the post treatment period. [8]

It is unknown whether patients without cancer experience insomnia, depression or anxiety associated with a USOC referral for head and neck cancer. Given a small proportion of these

referrals result in a diagnosis of head and neck cancer, we investigated the psychological impact of this referral.

This study aims to determine if there is any difference in median score for the following psychometric questionnaires: Insomnia Severity Index (ISI), Patient Health Questionnaire 9 (PHQ9) and General Anxiety Disorder 7 (GAD7) between benign and malignant patients prior to their referral appointment (baseline) and also if there is any difference between these two groups at follow up. The study also aims to assess the change from baseline to follow up scores for both the benign and malignant groups.

Materials and Methods

Data Collection

Questionnaires were given to 227 eligible patients attending the otolaryngology outpatient clinic at the Queen Elizabeth University Hospital between October 2020 and March 2021. Patients who met the eligibility criteria were those 16 years or older attending with a USOC referral. Information sheets were posted to all eligible patients prior to clinic attendance. This allowed patients to decide whether or not to participate as well as prepare questions before arrival.

Eligible patients completed the questionnaires prior to their clinic appointment. Patients were telephoned 2-4 weeks after their appointment to complete the questionnaires a second time – by which such time they will have been informed of their diagnosis. Patients were divided into a 'benign' and 'malignant group' depending on their diagnosis.

The Insomnia Severity Index

The ISI was used to assess the nature, severity and impact of insomnia.[16] The ISI uses a 5-point likert scoring system. (0 = No Problem, 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Very Severe) Total score for the ISI ranges from 0-28 and a cut-off score of 10 is 86.1% sensitive and 87.7 % specific for detecting insomnia cases. [9] A score between 0-7 indicates absence of insomnia, between 8-14 subthreshold insomnia, between 15-21 moderate insomnia and between 22-28 severe insomnia. Evidence has shown it to be a reliable self-report measure to evaluate perceived sleep difficulties and a sensitive measure to detect changes in perceived sleep difficulties with treatment. [10]

The Patient Health Questionnaire 9

The PHQ9 is used to diagnose depression. It is a 9-symptom checklist which patients can self-report the severity of each symptom on a 4-point Likert scale as 0 (Not at all), 1 (Several days), 2 (More Than Half The Days) or 3 (Nearly Every Day). [11] This generates a score from 0-27 with score of equal to or greater than 10 having a sensitivity and specificity of 88% for detecting major depressive disorder. [11] The PHQ-9 score is interpreted as mild (5-9), moderate (10-14), moderately severe (15-20) and severe depression (>=20).

The Generalised Anxiety Disorder 7 Questionnaire

The GAD 7 questionnaire screens for Generalised Anxiety Disorder and assesses its severity. The GAD 7 questionnaire is a 7-item checklist which scores the cardinal symptoms of generalised anxiety disorder on a 4-point Likert scale as 0 (Not At All), 1 (Several Days), 2 (More Than Half The Days) or 3 (Nearly Every Day). [12] This generates a score from 0-21 with a cut-off score of 10 having 89% sensitivity and 82% specificity for a diagnoses of generalised anxiety disorder. [12] The GAD-7 score can be interpreted as mild (5-9), moderate (10-14) and severe anxiety (>=15).

Statistical Analysis

Kolmogorov's Smirnoff testing was used to assess the normality of total scores for each questionnaire at baseline and at follow up. This revealed the spread of total scores were significantly different from a normal distribution ($p < 0.01$), for all questionnaires, at baseline and at follow up. Thus, we decided to report median values. Mann Whitney U testing was used to assess for differences in baseline median scores between benign and malignant groups as well as any difference in the follow up median scores between the benign and

malignant groups. The Wilcoxan sign-rank test was the paired test used to compare baseline and follow up questionnaire scores for each diagnostic group (malignant / benign). Analysis was performed using SPSS V 27.0.1.0.

Ethical Considerations

The questionnaires were databased anonymously and research ethics committee approval was granted for the study. Informed, written consent was obtained from all participants.

Results and Analysis

Patient Demographics

Of the 227 who filled the out questionnaires at their appointment, 208 (91.6%) were able to be contacted via telephone call for the follow-up consultation. The mean age was 49.05 years old and 126 (60.6%) patients were female. 113 (54.3%) were smokers or ex-smokers and 173 (83.2%) recorded alcohol intake within weekly recommended rates. 151 (72.6%) lived with their spouse, partner or family. 125 (60.1%) achieved a higher education qualification and 107 (51.4%) participants were employed on a full or part-time basis.

Patients in the benign group were significantly younger and significantly less likely to be a smoker or ex-smoker. Patients in the benign group were more likely to be employed or in full time education as well as being less likely to live alone than patients in the malignant group. See table 1 for all demographic information.

Diagnostic groups

Of the 208 patients included in the analysis, 185 (88.9%) received a benign diagnosis and 23 (11.1%) a malignant diagnosis. Of the 23 malignancies, 17 (8.2%) were diagnosed with a primary head and neck cancer. The most common benign diagnosis was 'No Abnormality Detected' seen in 57 (30.8%) of these patients. The most common malignant diagnoses were oral cancer seen in 6 (26.1%) patients) and laryngeal cancer seen in 6 (26.1%) patients)). Oropharyngeal cancer is the most common form of head and neck cancer globally and was seen in 5 (21.7%) of the patients with malignancies. The variety of benign and malignant diagnoses can be seen in Tables 2 and 3.

Insomnia Severity Index (ISI)

For the ISI, there was no significant difference in baseline median scores between benign and malignant groups ($p = 0.914$) with both median scores corresponding to 'subthreshold insomnia'. At follow up, there was a statistically significant difference in median score between benign and malignant groups ($p < 0.01$) with median score in the benign group corresponding to 'Absence of insomnia' and 'Moderately severe insomnia' in the malignant group.

There was a significant reduction in ISI score from baseline to follow up to follow up in the benign group ($p < 0.01$) indicating improved sleep. There was a significant increase in ISI score from baseline to follow up in the malignant group ($p <0.01$) indicating worsening sleep. Scores for the ISI are shown in Figure I.

Patient Health Questionnaire 9 (PHQ9)

For the PHQ9, there was no statistically significant difference in baseline median scores between the benign and malignant groups ($p = 0.254$) with median scores for both groups corresponding to 'Mild Depression'. At follow up, there was a statistically significant difference in median scores between the benign and malignant groups ($p < 0.01$) with the median score for the benign group corresponding to 'No depression' and the median score for the benign group corresponding to 'Moderately severe depression'.

There was a significant reduction in median GAD 7 scores from baseline to follow up in the benign group ($p < 0.01$) indicating less severe symptoms of depression. There was a significant increase the median score from baseline to follow up in the malignant group ($p <$

0.01) indicating more severe symptoms of depression. Scores for the PHQ9 are shown in Figure II.

Generalised Anxiety Disorder 7 Questionnaire

For the GAD7 questionnaire, there was no significant difference in baseline median scores between the benign and malignant groups ($p = 0.330$) with median scores for both groups corresponding to 'No Anxiety'. At follow up, there was a statistically significant difference in scores between the benign and malignant groups ($p < 0.01$) with the median score for the benign group corresponding to 'No anxiety' and the median score for the benign group corresponding to 'Severe Anxiety'.

GAD7 scores show a significant decrease from baseline to follow up in the benign group ($p < 0.01$) indicating improvement in the symptoms of anxiety. Median scores in the malignant group showed a significant increase from baseline to follow up in the malignant group ($p < 0.01$) indicating worsening in the symptoms of anxiety. Scores for the ISI are shown in Figure III.

We also recorded mean scores for each questionnaire at baseline and follow up and these are included in tables 4 and 5.

Discussion

Comparison of Benign and Malignant Groups

We showed that symptoms of insomnia, depression and anxiety in the malignant group were similar to that of the benign group prior to the appointment. At follow up, we showed that symptoms were significantly worse in the malignant group compared to the benign group. With regards to patient demographics, analysis showed that patients diagnosed with cancer at the clinic are significantly older and more likely to be a smoker / ex-smoker which are important risk factors for the development of head and neck cancer. [13]

Benign Group (Baseline versus Follow Up)

The significant improvement in the median scores in the benign group for all questionnaires suggests that there is likely a degree of sleep disturbance, depression and anxiety prior to the appointment which improves following a benign diagnosis. Whilst these symptoms appear to be mild, it is important noting that benign referrals make up the majority of these USOC referrals.

Malignant Group (Baseline versus Follow Up)

The significant deterioration in the median scores in the malignant group for all questionnaires is somewhat unsurprising, as a diagnosis of cancer is associated with significant psychological distress and existing literature shows the prevalence of insomnia, depression and anxiety to be high in head and neck cancer patients following their diagnosis. [14]

Head and Neck Cancer Rate

The cancer rate for patients in our sample was 11.1%, with 8.2% of these being primary head and neck cancers. This is similar to the findings of a large 2016 systematic review and meta-analysis which reported a pooled 2-week referral conversion rate for head and neck cancer rate of 8.8% (95% CI 7% - 10.7%). [15] However, a 2020 study showed a pick-up rate for head and neck cancer as low as 3% in patients attending urgent referrals in Glasgow. [4] It is unclear the reason for this increased pick-up rate in our sample. However, one possible explanation may be the impact of COVID-19, with most patients only wishing to attend hospital appointments if strictly necessary and with more severe symptoms.

Importance of the Study

Critics of the 2-week referral process have claimed that only a small proportion of people referred this way are diagnosed with cancer, that the referral has little effect on survival and that referring patients in this manner is expensive. Those in support of the process claim it ensures consistency in management of cancer patients and that patients value the process. Literature on the psychological impact of a 2-week urgent referral is limited and concerns other forms of malignancy such as breast and colorectal carcinoma. [16,17] Cornfold et al. conducted a qualitative study and found that woman referred via a two-week urgent referral experienced considerable anxiety from the time of their referral to diagnosis. They also identified that patients felt they needed more information about breast symptoms and the referral process itself. [16] Ndukwe et al. also conducted a qualitative study interviewing patients who had been referred under the two-week rule for suspected colorectal cancer. They concluded that patients appreciated the speed of the referral process and the

welcomed further investigations but the process caused them significant levels of anxiety and distress. They identified that two areas in which the psychological impact of the referral could be reduced would be by providing early psychological support as well giving patients more information about the investigative process. [17]

Cancer pick-up rates from these urgent referrals have been shown to be particularly low in several recent studies suggesting the pathway is being significantly overused. [4,18,19] Future measures to improve how we filter out the vast majority of benign patients might avoid these symptoms and improve the patient journey.

Study Strengths

Strengths of our study included a large sample of benign patients as well as using questionnaire which have been extensively validated. These questionnaires have also been shown to be sensitive to change which was crucial for the purpose of this study. The follow up rate in our study was also very good, with 208 (91.6%) of the originally consented patients completing the follow up questionnaires.

Study Limitations

The small size of the malignant group reduced the reliability of these findings. There was no other qualitative information on the patient's sleep or mental health recorded at follow up which may have been helpful in establishing the exact reasons for changes in score. Previous diagnosis of insomnia, depression and anxiety was not recorded which would have been useful as patients would be likely to report severe symptoms regardless of whether the appointment had been concerning them or not. While these questionnaires have undergone

extensive validation, little data exists on what a mean / median score for the general population would be which would have been useful to compare to.

Clinical Implications

This study's findings add weight to the proposition that the approach to urgent head and neck cancer referrals should be improved. This may be achieved through use of a head and neck risk calculator in the primary care setting. The head and neck risk calculator has been shown to have significant potential to improve health service delivery by reducing the number of inappropriately urgent referrals. [20] Reduction in the number of inappropriate referrals could avoid the adverse impacts of insomnia, depression and anxiety in the patients who would ultimately receive a benign diagnosis.

The management of head and neck cancer patients (and cancer patients generally) could be improved by the screening of newly diagnosed patients for insomnia, depression and anxiety. Early detection of these symptoms would allow them to be referred to the appropriate services and / or receive appropriate treatment to help manage these symptoms as they enter cancer treatment.

Conclusion

Prior to a referral for suspicion of head and neck cancer, patients with both benign and malignant conditions experience similar levels of insomnia, depression and anxiety. In the patients who received a malignant diagnosis, insomnia, depression and anxiety worsened. In the patients who received a benign diagnosis, scores for all questionnaires significantly improved. Improvement of these scores at follow up indicates that feelings of insomnia depression and anxiety were in part, related to the clinic attendance.

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Tables and Charts

TABLE I

DEMOGRAPHIC INFORMATION

Demographic Variable	**All patients (n = 208) Number (%)**	**Benign Group (n = 185) Number (%)**	**Malignant Group (n = 23) Number (%)**	**P - Value**
Sex (n (%)				
• Male	82 (39.4)	72 (38.9)	10 (43.4)	>0.05
• Female	126 (60.6)	113 (61.1)	13 (56.6)	>0.05
Age (mean (range); years)	49.05 (16-87)	47.84	58.78	**<0.05**
Smoking Status (n (%))				
• Current Smoker / Ex-smoker	113 (54.3)	96 (51.9)	17 (73.9)	**<0.05**
• Never Smoked	95 (45.7)	89 (48.1)	6 (26.1)	**<0.05**
Alcohol Intake Status (n (%))				
• Within recommended UK limit	173 (83.2)	155 (83.8)	18 (78.3)	>0.05
• More than recommended UK limits	35 (16.8)	30 (16.2)	5 (21.7)	>0.05
Housing (n (%))				
• Married / living with partner / family	151 (72.6)	136 (73.5)	15 (65.2)	>0.05
• Lives alone	49 (23.6)	42 (22.7)	7 (30.4)	>0.05
• Residential care	8 (3.8)	7 (3.8)	1 (4.3)	>0.05
Employment (n (%))				
• Full or part-time employment	107 (51.4)	98 (53.0)	9 (39.1)	**<0.05**
• Full time education	15 (7.2)	15 (8.1%)	0	**<0.05**
• Not employed or retired	86 (41.4)	72 (38.9)	14 (60.9)	**<0.05**
Education (n (%))				
• College / university qualification	125 (60.1)	112 (60.5)	13 (56.5)	>0.05
• No higher education	83 (39.9)	73 (39.5)	10 43.5)	>0.05

Table I: Demographic information for all patients and main diagnostic groups.

p – values in bold represent a significant difference in a characteristic between benign and malignant groups. (n = number of participants)

TABLE II:

BENIGN DIAGNOSES

Benign Diagnosis	**Number of participants** **n = 185** **Number (%)**
No abnormality detected	57 (30.8)
Globus	11 (5.9)
Benign Larynx	12 (6.5)
Reactive Lymph Nodes	34 (18.4)
Benign Thyroid	21 (11.4)
Benign Salivary	12 (6.5)
Benign Oropharynx	7 (3.8)
Benign Neck	25 (13.5)
Benign Oesophagus	6 (3.2)

TABLE III:

MALIGNANT DIAGNOSES

Malignant Diagnosis	**Number of participants** **n = 23** **Number (%)**
Malignant Oropharynx	5 (21.7)
Malignant Oral	6 (26.1)
Malignant Larynx	6 (26.1)
Malignant Thyroid	2 (8.7)
Lymphoma	2 (8.7)
Metastases	2 (8.7)

TABLE IV:

Mean and standard deviation scores for all questionnaires at baseline and follow up in the benign group.

	Baseline (ISI)	Follow Up (ISI)	Baseline (SCI)	Follow Up (SCI)	Baseline (PHQ9)	Follow Up (PHQ9)	Baseline (GAD7)	Follow Up (GAD7)
Mean	10.75	6.40	17.69	21.82	7.75	4.92	6.73	3.66
Std. Deviation	7.076	6.906	8.575	8.750	6.870	6.421	5.875	5.383

TABLE V:

Mean and standard deviation scores for all questionnaires at baseline and follow up in the malignant group.

	Baseline (ISI)	Follow Up (ISI)	Baseline (SCI)	Follow Up (SCI)	Baseline (PHQ9)	Follow Up (PHQ9)	Baseline (GAD7)	Follow Up (GAD7)
Mean	10.78	16.87	16.35	14.17	10.09	13.30	8.52	12.61
Std. Deviation	7.822	8.651	9.053	10.030	8.399	9.276	7.627	8.856

Bullet Point Summary

- Cancer detection rates from urgent head and neck cancer referrals remains low.
- It is well established that head and neck cancer patients are at an increased risk of insomnia, depression and anxiety from the time of diagnosis and throughout their treatment pathway.
- No study has investigated the impact of an urgent suspicion of cancer referral on the patients that ultimately receive a benign diagnosis.
- Prior to an appointment for suspected head and neck cancer, all patients regardless of ultimate diagnosis experience similar levels of insomnia, depression and anxiety.
- Once patients with malignancy receive their diagnosis, they show worsening of these symptoms.
- Once patients receive a benign diagnosis, their insomnia, anxiety and depression symptoms resolve, indicating these symptoms were in part, related to clinic attendance.
- Attempts to improve the quality of urgent head and neck cancer referrals could reduce the number of benign patients who experience these adverse symptoms of insomnia, depression and anxiety.