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Prevalence and associated factors of psychological distress among patients with oral cancer in the selected tertiary care institutes in Sri Lanka: a combined cross-sectional and case-control study

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ABSTRACT

Introduction Oral cancer represents the most prevalent malignancy among Sri Lankan males. This aggressive disease is associated with significant psychological distress, driven by disfigurement and impairments of vital functions.

While the detrimental impact of psychological distress on patients with oral cancer is well documented, its prevalence and associated determinants remain underexplored in the Sri Lankan context. This study aims to evaluate the prevalence and identify the factors associated with psychological distress in a selected cohort of patients with oral cancer in Sri Lanka.

Methods A hospital-based cross-sectional study was conducted among 355 patients with oral cancer to determine the prevalence of psychological distress. Additionally, a nested case-control study comprising 140 patients per group was carried out to evaluate the factors associated with psychological distress. Multivariate logistic regression analysis was performed to identify significant associated factors of psychological distress.

Results The prevalence of psychological distress among patients with oral cancer was 31.0% (95% CI=27.8–35.3%). Being <50 years of age (adjusted OR (AOR)=1.2, 95% CI=0.7–1.7, p=0.006), having pain (AOR=44.7, 95% CI=34–53.21, p=0.001), late stages of cancer at the diagnosis (AOR=10.7, 95% CI=1.07–28.78, p=0.04), being worried about basic functional disabilities (AOR=11.4, 95% CI=10.3–14.8, p=0.006) and the two psychological factors—*worry* ("Other people *worry* about me more than I do"; AOR=5, 95% CI=2.8–6.9) and *anger* ("I feel very *angry* about what has happened to me"; AOR=12.1, 95% CI=6.8–15.4)—emerged as significant independent factors that were associated with increased risk of psychological distress among patients with oral cancer.

Conclusion Approximately one-third of patients with oral cancer in the selected tertiary care hospitals were found to experience psychological distress, highlighting its high prevalence in this population. The identification of key factors associated with psychological distress provides valuable insights for the development of targeted

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Psychological distress in patients with oral cancer negatively impacts the treatment outcomes and patient's quality of life. However, the prevalence and associated factors of psychological distress in Sri Lankan patients with oral cancer are unknown. This lack of knowledge hinders efforts to improve treatment success and patients' quality of life.

WHAT THIS STUDY ADDS

⇒ Sri Lankan patients with oral cancer experience high rates of psychological distress, with several significant contributing factors.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study findings can guide a national programme to identify and support Sri Lankan patients with oral cancer experiencing psychological distress, promoting early access to palliative care.

intervention strategies aimed at mitigating psychological morbidity among patients with oral cancer.

INTRODUCTION

Oral and pharyngeal cancers are the sixth most common type of cancer worldwide.[1] In Sri Lanka, oral cancer is the leading cancer among males, accounting for 15.5% of all newly diagnosed cancer cases in 2021.[2] Furthermore, there has been a notable increase in the age-standardised incidence rates of oral cancers, particularly among Sri Lankan males, from 9.8 per 100 000 in 2005 to 23.1 per 100 000 in 2021.[2]

Cancer diagnosis and treatment are often associated with a range of physical

and psychological challenges that contribute to significant psychological distress.[3] [4] Psychological distress is a complex, multifactorial emotional experience encompassing physical, psychological, social, spiritual and cultural dimensions, and it adversely affects both the quality of life and treatment outcomes of patients.[5] The reported prevalence of psychological distress among patients with cancer varies widely, ranging from 20% to 70% across different studies.[6–9] However, research specifically focusing on psychological distress in patients with oral cancer is limited, with existing studies indicating a prevalence ranging from 25% to 41% in this population.[10–13]

Although research on the negative impact of untreated psychological distress specifically in patients with oral cancer is limited, studies involving patients with other cancer types have demonstrated that unaddressed psychological distress can lead to poor adherence to medical treatment, delayed recovery, diminished quality of life, difficulties in adjusting to life post-treatment, increased risk of tumour recurrence and reduced survival rates.[5] [7] [14–17] Therefore, the early identification and management of psychological distress in patients with oral cancer should be considered a crucial component of comprehensive oncological care.[5]

Effective management of psychological distress requires a clear understanding of its contributory factors. Several factors have been identified as contributing to the development of psychological distress in patients with cancer. The National Comprehensive Cancer Network guidelines on distress management categorise these risk factors into (a) health-related, (b) personal, (c) spiritual, (d) social and (e) other risk factors, including sexual and physical abuse, substance use disorders and other mental health conditions.[5] A critical review of the literature reveals that while the categorisation of these factors may vary across studies depending on the specific psycho-social context, four core categories consistently emerge: socio-demographic characteristics, medical or disease-related factors, social factors and psychological factors.[18–32] Investigating the factors associated with psychological distress among patients with oral cancer in Sri Lanka is crucial as the management of this condition relies heavily on identifying and addressing these specific factors.

Although oral cancer is the most prevalent cancer among Sri Lankan males, to the authors' knowledge, only one study has assessed psychological distress in this patient population. This study, conducted at a hospital in Southern Sri Lanka, used the General Health Questionnaire-12 to measure psychological distress and reported a prevalence of 69%.[33] To date, no studies have been conducted to identify the factors associated with psychological distress specifically in patients with oral cancer in Sri Lanka.

Exploring psychological distress and its associated factors in patients with oral cancer is crucial, particularly in Sri Lanka, where oral cancer is the leading cancer among males and ranks among the top 10 cancers in females.[2] Moreover, many patients in this population come from relatively low socio-economic backgrounds, which heightens their vulnerability and contributes to elevated levels of psychological distress.[34] In addition, a significant proportion of cancer patients in Sri Lanka present at advanced stages (stages III and IV), which further exacerbates the psychological burden.[2] Consequently, if psychological distress in patients with oral cancer remains undiagnosed and untreated, it is likely to negatively impact disease outcomes, quality of life and place a considerable burden on the healthcare system. This study aims to examine the prevalence and associated factors of psychological distress in patients with oral cancer in Sri Lanka.

METHODS
This study is reported in line with the Strengthening the Reporting of Observational Studies in Epidemiology checklist for combined studies (online supplemental appendix I).

Study design
We conducted a descriptive cross-sectional multicentre study with a nested case-control study.

Figure 1 shows a schematic presentation of the nested case-control study.

Study setting and period
The study was conducted from September 2019 to January 2020 in selected tertiary care units providing oral cancer treatment in Sri Lanka (The National Dental Hospital (Teaching) Sri Lanka, Colombo South (Teaching) Hospital, Apeksha Hospital—Maharagama and Karapitiya (Teaching) Hospital).

Study participants
The inclusion criteria were patients who had received a definitive diagnosis of oral cancer, with clear communication about the diagnosis at least 1 month before being recruited for the study. Additionally, the patient could be able to communicate and read well in the Sinhala language. The patients who had recurrent oral cancer, had a history of psychiatric diseases, had been already treated for psychological distress at the Psychological Counseling, Spiritual and Social Development Unit, Apeksha Hospital, were receiving end-of-life palliative care and with other severe comorbidities were excluded from the study. All patients with oral cancer who fulfilled the eligibility criteria and gave informed consent were recruited for the study.

For the case-control study, the participants were a subset of the study units who took part in the prevalence study. The participants were divided into two groups as cases and controls. The cases included patients who were identified as having psychological distress after applying the Sinhala-validated Distress Thermometer (cut-off value ≥4).[35] The controls included patients who were identified as **not** having psychological distress after applying
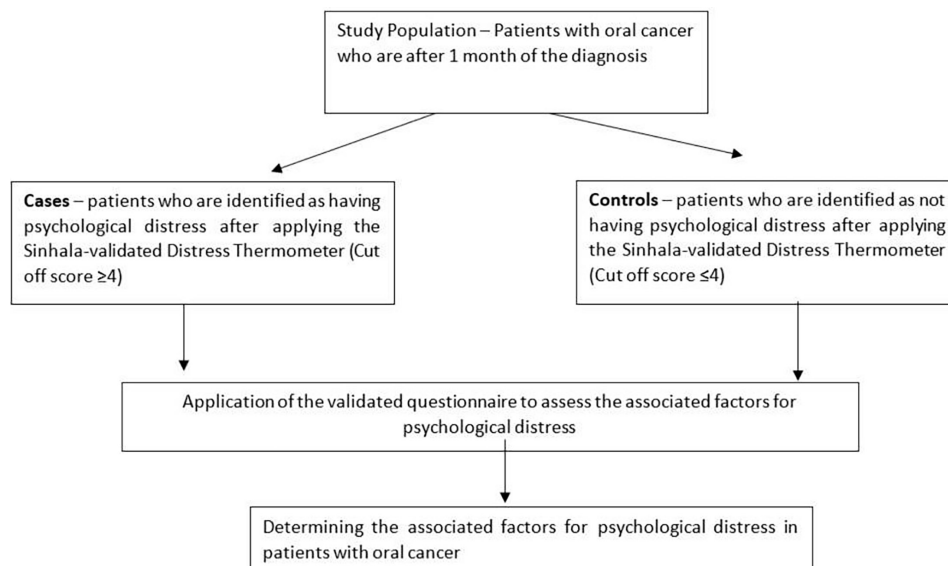
Figure 1 Schematic presentation of the case-control study.

the Sinhala version of validated Distress thermometer (cut-off value <4).

There were 140 cases present in the prevalence study, and all of them were recruited for the case-control study as cases. There were 215 patients who fulfilled the criteria for controls in the prevalence study. Yet as the cases:controls ratio was 1:1, only 140 controls were selected for the case-control study out of 215 eligible controls in the prevalence study. This was accomplished by including the first 140 patients according to the date of recruitment who scored a Distress Thermometer value <4 in the prevalence study. It was assumed that there was no bias introduced due to this method of control selection since the study period was as short as 4 months.

Procedure

The patients were approached in the waiting area while awaiting their appointment at the clinic. The eligible patients who gave their consent for the study were first given a questionnaire to collect socio-demographic details, followed by the Sinhala version of validated Distress Thermometer. Those who scored ≥4 on the Distress Thermometer (cases) and the first 140 patients who scored <4 (controls) were given an additional questionnaire to assess the associated factors for psychological distress. The data collection was carried out by the principal investigator with the support of a trained data collector on specified days allocated for each cancer treatment centre.

Study size

The sample size for the prevalence study was calculated with a Z value of 1.96 at a 95% CI and 0.05 precision. The anticipated prevalence of psychological distress among patients with oral cancer was 30.7%,[36] and for a 10% non-response rate, the sample size for the prevalence study was 355.

For the unmatched case-control study, the highest sample size gained for the estimated OR of the associated factors was 65 per arm after adjusting for a non-response rate of 5%. However, since this case-control study was carried out on a subset of the prevalence study, all the 140 cases that were presented in the prevalence study were recruited. The case:control ratio was 1:1.

Data measurement

The Sinhala version of validated Distress Thermometer was used as the screening tool to identify patients with oral cancer who had psychological distress.[35] Based on a conceptual framework (online supplemental appendix II), a multicomponent, interviewer-administered questionnaire (online supplemental appendix III) was developed to determine the associated factors of psychological distress. The questionnaire was assessed for judgemental validity by 10 experts in the fields of oncology, oro-maxillo-facial surgery, sociology, public health and psychology and was pre-tested on 20 patients with oral cancer at Gampaha District General Hospital which is another tertiary care institute providing cancer care.

The questionnaire consisted of nine domains; (1) socio-demographic background, (2) socio-economic background, (3) disease-related factors, (4) perceived worry related to physical and practical issues, (5) social factors, (6) psychological factors, (7) spiritual factors, (8) existing levels of knowledge on cancer and (9) satisfaction with healthcare.

Statistical methods

The SPSS V.21 was used for the data analysis. The clinically validated cut-off point of 4 was used to identify the presence of psychological distress.[35] The adjusted prevalence was presented considering the psychometric properties of the Distress Thermometer.

The bivariate cross-tabulations were used to assess the associated factors for psychological distress. The strength of each variable as an associated factor for psychological distress was calculated by unadjusted OR with a 95% CI (online supplemental appendix IV). The multivariate analysis was performed using the Logistic Regression analysis to compute the adjusted OR (AOR) of the factors. The goodness of fit of the model was assessed with Hosmer and Lemeshow test.

Patient and public involvement

The questionnaire which was used for the case-control study to assess the associated factors for psychological distress was developed based on a conceptual framework (online supplemental appendix II). This conceptual framework was constructed through triangulation of the findings of a few qualitative studies that involved patients with oral cancer. Therefore, patients were involved in focus group discussions and in-depth interviews to seek their input on associated factors of psychological distress.

RESULTS

Patient characteristics

The participants had a mean age of 56.72 (SD 10.57), and most of them (76.1%) were over 50 years of age and were males (70.4%). The majority (76.3%) were Sinhalese. Results indicated that 76.1% had attained an educational level up to grade 10 and 35.5% were unemployed (table 1).

Psychological distress prevalence estimations

We found that the patients with oral cancer had an overall adjusted prevalence of 31.0% (95% CI=27.8–35.3%) for psychological distress. In particular, the age group <49 (60.1%, 95% CI=44.8–73.8, p=0.0001) included the highest proportion among them. Moreover, considering the marital status, the married group (35.6%, 95% CI=30.3–41.9%, p=0.01) showed a statistically significant proportion of psychological distress in the study cohort (figure 2).

Factors associated with psychological distress

We looked at a number of parameters to find factors independently associated with psychological distress. Among them, being below 50 years of age compared with being 51 and above (AOR=1.2, 95% CI=0.7–1.7), presence of pain compared with having no pain (AOR=44.7, 95% CI=34.5–53.21), cancer presenting at late stages compared with presenting at an initial stage (AOR=10.7, 95% CI=1.07–28.78), being worried about basic functional disabilities compared with not being worried (AOR=11.4, 95% CI=10.3–14.8) and the two psychological factors—*worry* "Other people *worry* about me more than I do" compared with not concerned about other people worrying (AOR=5, 95% CI=2.8–6.9) and *anger* "I feel very *angry* about what has happened to me" compared with not being angry about what has happened (AOR=12.1, 95% CI=6.8–15.4)—significantly increased the odds of getting psychological distress in patients with oral cancer. The Hosmer-Lemeshow goodness-of-fit test (p=0.81) indicated that the model was a good fit (table 2).

DISCUSSION

The current study demonstrated a 31.0% prevalence of psychological distress. We found that certain critical factors, namely those below 50 years of age compared with those who were aged 50 and above, having pain compared with not having pain, cancer presenting at late stages compared with presenting with cancer at an early stage, being worried about basic functional disabilities compared with not being worried and the two psychological factors—*worry* and *anger* ("Other people *worry* about me more than I do" and "I feel very *angry* about what has happened to me")—showed a significant association compared with their reference group with increased distress among patients with oral cancer. These findings emphasise the importance of addressing psychological distress early and comprehensively, incorporating physical, psychological and social factors, especially for younger patients and those diagnosed with advanced stages of cancer.

Prevalence

Many studies revealed that patients with all types of cancer varied in psychological distress from 20% to 70%, supporting the findings of the current prevalence study.[4–9] This could be mainly due to the heterogeneity of study methods, such as the variations in the target population (not solely patients with oral cancer, stage of cancer, type of treatment received), differences in study designs and the use of different measurement tools to assess psychological distress.

| Table 1	Descriptive characteristics of the participants	
Characteristic	**Number (n=355)**	**Percentage**
Age (years), mean age=56.72 (SD 10.57)		
<50	85	23.9
≥50	270	76.1
Sex		
Male	250	70.4
Female	105	29.6
Ethnicity		
Sinhala	271	76.3
Non-Sinhalese*	84	23.7
Level of education		
Up to grade 10	270	76.1
Grade 11 and above	85	23.9
Occupation category		
Unemployed	126	35.5
Employed	229	64.5
*Tamil, Moor and other nationalities.		
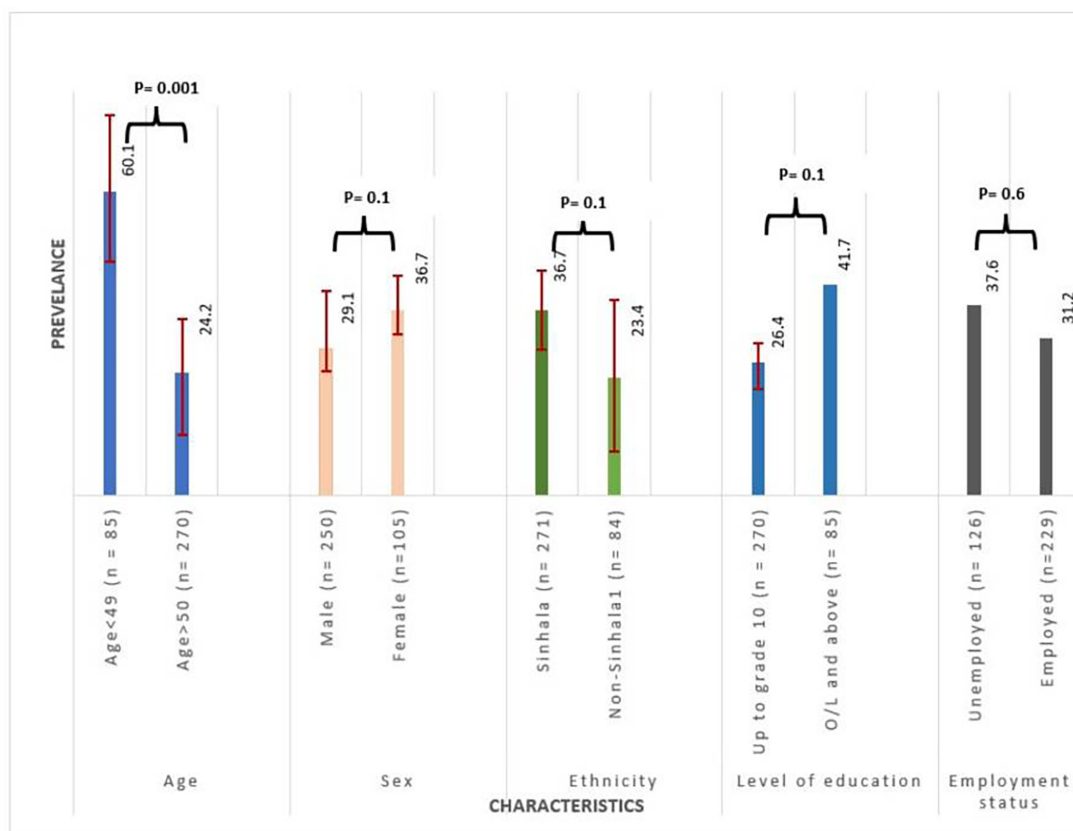
Figure 2 Prevalence of psychological distress.

Despite limited research on psychological distress among patients with oral cancer using Distress Thermometer as the screening tool, a study conducted by Wang *et al* in 2018 reported a prevalence of 58.2% at ≥4 cut-off score on the Distress Thermometer, thus replicating the cut-off score of the present study.[37] The higher prevalence than in the present study could be due to variations in sample characteristics and the stage of the treatment process. For example, the Chinese patients with oral cancer included recurrence cases and those who were in end-stage palliative care which were among the exclusion criteria for the present study.

There are no studies conducted solely on the prevalence of psychological distress among patients with oral cancer in Sri Lanka. However, the study by Weeratunga on patients with all types of cancers includes oral cancer. The screening tool used in the study was the General Health Questionnaire-12, and it was interviewer-administered, similar to the current study. The results showed the prevalence of psychological distress in patients with oral cancer to be 69%, thus indicating over twofold increase in prevalence than the current study. Such variations of the findings could be attributed to the difference in the screening tools used by the two studies and other methodological variations.[33]

Associated factors

We selected a case-control study to explore the associated factors for psychological distress in patients with oral cancer as opposed to a cross-sectional study which made the evidence stronger. However, many studies use the cross-sectional study design due to obvious constraints inherent to conducting research among patients with oral cancer.[38 39] We developed the study instrument to

Table 2 Associated factors for psychological distress of patients with oral cancer

Factor	SE	Adjusted OR	95% CI		P value
Being below 50 years of age	1.65	1.2	0.7	1.7.	0.006
Presence of pain	2.34	44.7	34.5	53.21	0.001
Late stage of cancer presentation	1.02	10.7	1.07	28.78	0.042
More worried due to basic functional disabilities	4.56	11.4	10.3	14.8	0.006
"Other people *worry* about me more than I do"	1.65	5.0	2.8	6.9	0.001
"I feel very *angry* about what has happened to me"	7.5	12.1	6.8	15.4	0.005

assess the associated factors for psychological distress, which was an interviewer-administered questionnaire based on the conceptual framework following a scientific process to develop new study instruments which assured the quality of data.[40] We carried out judgemental validation for the questionnaire which assured quality data collection. However, we would recommend comprehensive validation of this questionnaire in future studies.

We did not find associations with other socio-demographic factors except the younger patients had higher odds of getting psychological distress compared with the older patients. Grave's cross-sectional study in 2007 supported this finding by showing that there was no association of demographic factors (sex, race, rurality of residence) with psychological distress except for age where similar to the current study younger age was related to higher levels of distress ($r=-0.14$, $p=0.01$).[40] Additionally, this relationship of younger age increasing the psychological distress of patients with cancer is supported by a few other studies.[22 24 29 37 38]

A longitudinal study in eight low- and middle-income countries in Southeast Asia, a similar setting to the current study, revealed a controversial finding to the current study. This study revealed that being older (>45 years) reported slightly more psychological distress than participants who were younger (AOR=1.01, 95% CI=1.01–1.02).[27] However, we justify the findings of the current study by the Sri Lankan family structure and culture. Sri Lanka owns a very closely-knit family structure where the children are highly dependent on their parents as the Sri Lankan family is essentially the conjugal unit of husband, wife and dependent children. Therefore, it is rational to argue that younger and middle-aged groups of patients have a high responsibility for caring for their children and also a higher responsibility to their parents.[41] This could be one of the reasons why the levels of psychological distress are higher in the younger age group (50 and below) compared with the older group.

We found no association between socio-economic factors and psychological distress which was in contrast to the study carried out by Kimman, where they found high income was associated with lesser psychological distress,[27] and the findings of Mason in 2019, where the authors revealed that patients who did not have definite employment had more stress than the people who were employed (52.6% and 26.8%, respectively).[42] We could support the current study results against the controversial finding by the fact that Sri Lanka still owns a self-sufficient and well-bonded lifestyle where the family members, extended families, neighbours and relations see to the needs of a patient till the recovery.[41] Furthermore, Sri Lanka owns a well-established healthcare public service that offers free-of-charge patient care services at the point of delivery which assures decent financial protection for the patient.[2] Therefore, although there could be a socio-economic burden the impact on the psychological distress could be argued to be minimal.

We found that the two disease-related factors—having pain and presenting at late stages of cancer—demonstrated significant association with psychological distress among patients with oral cancer. This is mainly due to pain and advanced stage with multiple complications contributing to enhanced suffering and discomfort of the oral cancer survivor which increases the levels of psychological distress. Several studies support this finding, confirming pain to increase the risk of getting psychological distress in patients with cancer.[23 30 43 44] Kimman found the association between the cancer stage and psychological distress to be significant where the stage III patients were at a higher risk of psychological distress (AOR=2.73, 95% CI=2.40–3.07).[27] Another study conducted among a group of 1496 patients with heterogeneous cancer including head and neck cancers in China revealed that the advanced stage increased the risk of psychological distress (AOR=1.85,95% CI=1.424–2.405).[28] Therefore, the above studies supported the current study findings.

We found a significant association between 'being worried about basic functional disabilities and psychological distress'. This finding is in line with the majority of the studies in the literature.[44–47] Moreover, our finding of two psychological factors increased the odds of getting psychological distress in patients with oral cancer; *worry* "Other people *worry* about me more than I do", *anger* "I feel very *angry* about what has happened to me" could be supported by few studies which revealed that worry about the loved ones around and anger about one's self was associated with a high risk of psychological distress in patients with cancer.[44–47]

We used the findings of this case-control study for the development of the intervention package aimed at improving the psychological distress and quality of life of patients with oral cancer which was a valid implication of the study findings.[48] This was an early palliative care intervention package that consisted of six components The early palliative care intervention for patients with oral cancer had six components: (1) providing information, (2) addressing acute and functional issues, (3) nutritional care, (4) psychological support, (5) mindfulness therapy and (6) coordination of the financial allowance and the development and effectiveness of this study are presented elsewhere.[48]

Strengths and limitations
The deployment of the Distress Thermometer which was translated, cross-culturally adapted and validated to Sri Lanka as the Sinhala version is a strength of this study since our findings demonstrated high psychometric properties.[35] Another notable strength of this study is the development of the questionnaire to assess the associated factors for psychological distress of patients with oral cancer which was based on a conceptual framework that was developed through the triangulation method that involved patients' perspectives as well. Development of the conceptual framework was another component of the study which followed a scientific process.

Selecting a case-control study design instead of a cross-sectional study to assess the associated factors for psychological distress of patients with oral cancer and using logistic regression to address the confounding factor bias during data analysis prove the methodological rigour of the study.

We acknowledge a few limitations in the study. The deployment of the Distress Thermometer to classify the diseased and the non-diseased would have introduced a misclassification bias. Yet, this was minimised since the Distress Thermometer gained recognition for high diagnostic accuracy compared with the gold standard of diagnosis of consultant psychiatrists. Although we controlled the known confounders by multivariate analysis, we did not consider the unknown confounders and the interactions between the factors which is a limitation of the study.

The questionnaire used to gather information on associated factors went through judgemental validation only, which is a limitation of the study. We recommend that future studies should validate this questionnaire comprehensively with a factor analysis.

We identify the exclusion of any patient who was unable to communicate in Sinhala as a limitation since Sri Lanka is a country with multiethnicity and the ethnic and racial representation would not have been present. Hence, we recommend the necessity of replicating this study with more diverse population groups.

CONCLUSIONS AND RECOMMENDATIONS

We demonstrated that the prevalence of psychological distress among patients with oral cancer who attended the selected Public Tertiary Care Institutes in Sri Lanka was high as nearly 1/3 of patients with oral cancer suffer from psychological distress. Having pain, presenting at late stages of cancer, being worried about basic functional disabilities and the two psychological factors—"Other people *worry* about me more than I do" and "I feel very *angry* about what has happened to me"—and being below 50 years of age were significantly associated with psychological distress in patients with oral cancer.

Hence, these findings provide the rationale to convince policymakers to initiate a national-level programme to screen patients with oral cancer for psychological distress and initiate sustainable programmes for the provision of early palliative care.

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