

ABSTRACT

Introduction

Oral cancer denotes a multi-faceted public health problem. since, out of all cancers, the cancer of lip, tongue and oral cavity is the most common cancer among males in Sri Lanka. Oral cancer causes more psychological distress among patients because of the visibility of the anatomical location and the disruption of the vital activities of daily living such as eating, speaking and swallowing by the illness and treatment modalities. Psychological Distress (PD) defined as multifactorial unpleasant emotional experience with physical, psychological, social, spiritual and cultural dimensions, negatively impacts not only the quality-of-life of patients but their treatment outcomes as well. The magnitude and risk factors for psychological distress among oral cancer patients remain largely unknown in Sri Lanka. In this context the present study aimed at addressing that pertinent research, knowledge and service gaps within its scope as the first study of this nature conducted in Sri Lanka among oral cancer patients.

Objectives

To estimate the prevalence and associated factors of psychological distress, and effectiveness of a 'life situation improving intervention' among oral cancer patients attending selected tertiary care public hospitals in Sri Lanka.

Methods

Component 1- Validation and cross-cultural adaptation of Distress Thermometer (DT) and Problem List (PL)

The Distress Thermometer (DT) accompanied with the Problem List (PL) is a widely used ultra- short tool to screen PD among cancer patients. The DT and PL were translated, cross culturally adapted and validated to Sri Lanka. The Modified Delphi Technique was used for the cross-cultural adaptation. The judgmental and criterion validation where the gold standard was the Consultant Psychiatrist diagnosis were carried out for the DT.

Component 2 - Assess the prevalence of psychological distress among oral cancer patients

A hospital based cross sectional study was carried out among 355 oral cancer patients to assess the prevalence of psychological distress (PD) using the validated DT in component 1.

Component 3- Constructing a conceptual framework to assess associated factors of PD

Two qualitative studies were conducted among experts in psychiatry, psychology, sociology, oral cancer care surgeons (Oral & Maxillofacial Surgeons & Oncologists) and among oral cancer patients and caregivers to explore the associated factors of PD. Those inputs were triangulated with the evidence synthesized by an extensive literature search to develop the multidimensional conceptual framework for associated factors of PD among oral cancer patients. Moreover, same study gathered inputs from aforementioned respondents regarding the need for an intervention and necessary components of such an intervention to address PD among oral cancer patients which were used for 5th component of the study

Component 4- Assess the associated factors of PD

A case control study was conducted among 140 oral cancer patients per group which was a subset of the prevalence study. The cases and controls were selected using the Distress Thermometer validated in component 1 and the questionnaire which was developed based on the conceptual framework in the component 3 was used for data collection. The multivariate analysis was carried out to control for confounders and identify statistically significant factors associated with PD.

Component 5- Formulation of the 'life situation improving' package for oral cancer patients

A novel intervention package for oral cancer patients to improve their 'life situation' was formulated by triangulating study findings of literature review, in depth interviews with experts and patients with caregivers (carried out in component 3), complimented by an observational study at Apeksha Hospital the main tertiary care hospital dedicated for

cancer patients in Sri Lanka and the case control study findings. The contents of the novel intervention package were finalized through a nominal group discussion.

Component 6- Assessment of the effectiveness of the 'life situation improving' package for oral cancer patients

A training programme of Public Health Nursing Officers (PHNOs) was conducted in two sessions in order to deliver the intervention package.

A quasi-experimental study was conducted to explore the effectiveness of the novel 'life situation improving' intervention among oral cancer patients. The study was carried out on 55 controls and 55 cases. The effectiveness of the intervention was assessed by selected process and outcome indicators. Process indicators comprised of % information provided, % nutritional care provided, % Coordination of the financial allowance, % Addressing acute and functional issues, % providing mindfulness therapy. Outcome indicators included the mean DT score and sub dimensions of Quality of Life scores of intervention group and control group at baseline (T1), just after the intervention (T2), one-month after the intervention (T3) and 3-months after the intervention (T4).

Results

Component 1- Validation and cross-cultural adaptation of Distress Thermometer (DT) and Problem List (PL)

The DT revealed good judgmental validity and the optimal cut-off point was 4 with sensitivity of 91.8% (95% CI = 80.8% - 96.8%) and specificity of 78.3 % (95% CI =64.4% - 87.7%). The test re-test reliability of DT was excellent (Kappa coefficient 0.894). The PL demonstrated high judgmental validity. Its internal consistency of items was excellent in the sub-scales of psychological problems (KD-20 = 0.9), and physical problem (KD-20 = 0.9) however, the internal consistency of practical problems (KD-20 = 0.4), social problems (KD-20 =0.3) and spiritual problems (KD-20 = 0.6) did not demonstrate high internal consistency since the KD-20 values were below 0.7.

Component 2 - Assess the prevalence of psychological distress among oral cancer patients using the validated DT.

The prevalence of PD among oral cancer patients was 31.0% (95% CI = 27.8%- 35.3%).

Component 3- Constructing a conceptual framework to assess associated factors of PD

The conceptual framework for the associated factors of PD of oral cancer patients consisted of 8 main domains; 1. socio-demographic factors, 2. socio-economic factors, 3. psychological factors, 4. satisfaction with the health care, 5. spiritual factors, 6. existing levels of knowledge on cancer, 7. social factors and 8. disease- related factors.

Component 4- Assess the associated factors of PD

After adjusting for confounding factors by multivariate analysis, being <50 years of age (Adjusted OR= 1.2, 95% CI= 0.7- 1.7, p= 0.006), having pain (Adjusted OR= 44.7, 95% CI= 34-53.21, p=0.001), late stages of cancer at the diagnosis (Adjusted OR= 10.7, 95% CI= 1.07- 28.78, p=0.04), being worried about basic functional disabilities (Adjusted OR= 11.4, 95% CI= 10.3- 14.8, p=0.006) and the two psychological factors (“Other people worry about me more than I do” (Adjusted OR= 5.0, 95% CI= 2.8-6.9, p=0.001) and “I feel very angry about what has happened to me” (Adjusted OR= 12.1, 95% CI= 6.8- 15.4,p=0.005) emerged as significant independent factors that were associated with PD in oral cancer patients.

Component 5- Formulation of the ‘life situation improving’ package for oral cancer patients

A feasible, novel ‘life situation improving’ intervention package consisted of; (1) providing information, (2) addressing the acute and functional issues – pain management, wound care and rehabilitation of the basic functions, (3) Nutritional care, (4) Co-ordination for financial assistance, (5) Providing Psychological support (6) Mindfulness Therapy. This package linked the hospital and community setting and was delivered in 3 sessions where the 1st session was delivered by the principal investigator (PI) and the last two sessions by the PHNO.

Component 6- Assessment of the effectiveness of the ‘life situation improving’ package for oral cancer patients

The training programme which was carried out for the PHNOs in two-sessions revealed effectiveness after both sessions, at the reaction level (100% perceived satisfaction), learning level (significant improvement in pre and post knowledge mean scores- $p=0.0009$), behaviour level (110 home visits made post training programme) and results level (Median DT score of intervention group = 3 and control group= 2, $p=0.009$).

The process indicators within the intervention group (IG) showed that there was a high reception of the intervention by the receivers where it showed high performance in each component of the intervention package (Information provision- 74.5%, Nutritional care 69.1%, Coordination of the financial allowance 81.2%, Addressing acute and functional issues 89.3%, providing mindfulness therapy 89.1% etc.) and the highest reception was evident in mindfulness therapy (89.1%). The comparison of the process indicators between the intervention group (IG) and control group (CG) showed that the performance of all the components were high in the intervention group which was significant (Information provision - IG=.74.5%, CG=63.6%, $p=0.001$ / Nutritional care- IG=69.1%, CG= 16.4%, $p=0.02$ / Coordination of the financial allowance- IG= 70.1%, CG= 34.5%, $p=0.03$ / Patients who were in pain- IG = 7.3%, CG= 32.7%, $p=0.01$ / Providing psychological support and mindfulness therapy- IG=78.2%, CG=47.2%, $p=0.001$).

When assessing effectiveness of the novel intervention using quasi experimental study, it was found that there was no significant difference in the baseline variables of the control and study groups. The DT scores within the intervention group showed significant improvement from the baseline to 3 months after the intervention (T1 = 6.9 to T4=3.5, $P=0.0001$). The control group also demonstrated a slight decrease (T1=6.8 to T4=5.6, $p=0.0001$) in the DT score which was much lesser than the intervention group. Moreover, when considering the post intervention time points (T2, T3, T4) the DT score indicated an increase over the time in both groups but the magnitude of increase is much lower in the IG (T2=2.4, T3= 3.1, T4= 3.5, $p=0.0001$) when compared with the CG (T2= 4.2, T3= 5.1, T4= 5.6, $p=0.0001$). When comparing the mean scores of Quality of Life (QOL) dimensions between intervention group and control group showed that all scores

improved throughout assessment points but the magnitude of improvement was more in intervention group ($p=0.0001$).

Conclusions and Recommendations

Component 1

The translated, cross culturally adapted Sinhala version of Distress Thermometer deemed to be a valid and reliable ultra-short screening tool to detect psychological distress among Sri Lankan oral cancer patients. The adapted Problem List for the Sri Lankan context of oral cancer patients was a valid tool to be accompanied with the DT in a busy clinic for triaging for psycho-social supportive care needs. However, PL should be used cautiously for the domains of practical problems, social problems and spiritual problems as the reliability was relatively low indicating further explorations.

Component 2

Almost one third of oral cancer patients in the selected tertiary care hospitals suffer from PD, and this is a high prevalence.

Component 3

The multidimensional conceptual framework on associated factors of psychological distress among oral cancer patients comprised of 8 domains: socio-demographic, socio-economic, psychological factors, satisfaction with the health care, spiritual factors, existing levels of knowledge on cancer, social factors and disease related factors.

Component 4

Having pain, presenting at late stages of cancer, being worried about basic functional disabilities and the two psychological factors of “Other people worry about me more than I do” and “I feel very angry about what has happened to me” were significantly associated with psychological distress among oral cancer patients. Moreover, younger oral cancer patients less than 50 years of age were more prone to suffer psychological distress than their older counterpart.

Component 5

The multi-component novel intervention package aimed at improving life situation of oral cancer patients addressed an array of well-recognized unmet psychosocial supportive care needs of oral cancer patients spanning for many dimensions.

Component 6

The existing category of PHNO already owned the required knowledge to deliver palliative care to oral cancer patients by building their capacity on existing base.

The novel 'life situation improving' intervention package demonstrated its effectiveness in improving PD and QOL of oral cancer patients within the period of follow up. The process indicators comparing the intervention group and the control group demonstrated sufficient evidence to speculate that the observed improvements in PD and QOL sub dimensions in the oral cancer patients in the IG were due to the novel intervention package, since the process indicators showed high performance in the IG when compared with the CG for each component of the intervention package.

Hence, it is recommended to incorporate the Distress Thermometer as the screening tool for PD among oral cancer patients and the intervention package to the existing health system to address their unmet problem of PD in oral cancer patients, throughout the cancer trajectory.

Key words: Psychological Distress, Health Related Quality of Life, Oral Cancer, Distress Thermometer, Mindfulness Therapy, Psychosocial intervention