CHAPTER-1
INTRODUCTION

1: INTRODUCTION

1.1 Oral cancer

1.1.1 Incidence and mortality

Oral cancer ranks seventeenth most common in the world while ranking second most common cancer in India. The incidence of oral cancer is 2% globally while for the Indian population it is 10.3%. In the Indian population oral cancer is preceded by Carcinoma Breast and followed by Carcinoma Cervix uteri. It is the most common cancer among males and the fourth most common cancer in females. [1,2]

1.1.2 Tobacco as a risk factor

India is one of the highest producers and consumers of tobacco in the world and hence contributes to the largest number of newly diagnosed cases of oral cancer annually. Indian population also has very poor oral health indicators compared to its western counterparts. Overwhelming scientific evidence shows that tobacco is a common causative agent and a risk factor for abysmal oro-dental health and oral cancer.[3] Our population has both poor oral health along with high tobacco consumption which results in a faster transition of oral premalignant lesions to oral carcinoma.

1.1.3 Periodontitis as a risk factor.

Various case-control and cross-sectional studies have shown Periodontitis as an independent risk for oral carcinoma.[4-6] Javed et al. in their systematic review and meta-analysis by Gopinath et al. have reported the same findings.[7,8] Indian population has a higher incidence of periodontitis and tobacco consumption; hence these conditions predispose our population to be at much high risk of oral cancer compared to the other populations.

1.1.4 Oral hygiene status and care protocol

There are various reasons for suboptimal to poor oral care among the Indian population and especially those with the diagnosis of oral cancer. The main reason is the lack of awareness of oral health and limited government aid for the National oral health program. Hasim et al. in their International Head And Neck Cancer Epidemiology (INHANCE) consortium reported that a good oral hygiene status, frequent dental visits, and adequate brushing at least once per day significantly reduce head and neck carcinoma risk.[9]

The majority of our patients do not get preventive and supportive oral care from the point of diagnosis of cancer and thereafter as part of the routine protocol in most of the cancer centers across the country. This is because of the lack of integration of dental experts in decision-making and as part of the supportive care team of the oncology unit. Very few centers in India have a dental expert as an active part of the cancer care team. They provide supportive, preventive, and rehabilitation care to these patients. Patients become aware of these needs only when the side effects of the cancer therapies are presented with.

To the best of our knowledge, there are no national guidelines in India, as of now on standard oral care protocol to be followed by the oncology professionals in patients with head and neck carcinoma. Based on our experience and training we had developed an institutional oral care protocol for a resource-limited setting like ours. We are providing care as per the Supportive Oral Care Protocol (SOCP) in our center for the last few years. The introduction of SOCP has reduced many oral dental complications such as osteoradionecrosis (ORN) of the jaw and radiation caries. It has improved oral functional efficiency by reducing the known side effect of cancer therapies and thus improving the oral health-related quality of life (OHRQOL) in our patients. One of the objectives of our study was to validate our SOCP and document it as a standard of oral care for cancer patients in a resource-limited setting like ours.[10]

1.2 Fluoride recommendation for chemo-radiotherapy patients

Dental decay is one of the major side effects of radiotherapy.[11] Fluoride is a well-established agent for the prevention of dental decay. It is recommended for its protective use in both professional and home applications.[12, 13] The majority of studies have been done on the systemic healthy adolescent population.[14, 15] There are very few studies for patients with head and neck carcinoma and therefore they do not provide conclusive results to form evidence-based guidelines in this subset of the population.[16-18] Landmark studies in the 1940s on the topical use of fluoride gel and varnish conducted by Knutson et al. and Galagan et al. reported caries reduction ranging from 30 to 40 percent from the use of topical fluoride. [19,20] These studies made a framework for the recommendation for fluoride in children. Based on these

results, projections were made regarding fluoride recommendations for the adult population.

The mode, duration, and frequency of use are variable in literature with very less available data on specific treatment needs for oral cancer patients. To explore such requirements in these patients we planned to observe the need for fluoride use and compare the type and frequency of use of topical fluoride

1.3 Xerostomia and the need for Fluoride

There is a specific type of dental decay known as radiation caries which is the hallmark of cancer patients who have received chemo-radiotherapy (CT-RT) in the region of the oral cavity.[21] Patients receiving Chemotherapy and radiotherapy are classified as high risk for caries due to altered saliva resulting in xerostomia.

American dental association in a landmark paper on the clinical recommendation for the use of topical fluoride has classified patients with xerostomia as a high-risk category.[22] All these recommendations were formulated based on data and the needs of children and adolescents at risk of caries. Specific needs of oncology patients were not assessed in depth.

In our experience, there is a higher incidence of decay during the first year after completion of chemo-radiotherapy in our patients. This is mainly due to the sudden onset of xerostomia, low awareness, and difficulty to adhere to adequate oral hygiene. Inadequate oro-dental professional care before, during, and after completion of the cancer treatment also results in radiation caries.

Keeping this in consideration we proposed the use of a more stringent monthly professional topical fluoride application regime in the first year post-radiotherapy.

This was done along with home use of fluoride mouth rinse and fluoride toothpaste. We compared neutral sodium fluoride gel and varnish use at monthly and quarterly frequencies for the first year after radiotherapy. We planned to analyze the clinical benefit of using the proposed fluoride type and frequency for our patients. To the best of our knowledge, till the writing of this dissertation, no such study has been reported before.

Radiation caries start at a faster rate in a matter of weeks and hence an effective plan is essential to address this known problem. As a part of our SOCP, we provide professional fluoride application before cancer treatment. After completion of chemo-radiotherapy fluoride is applied on monthly basis for the first year, and after that every quarter for life long. NCCN guidelines suggest quarterly topical fluoride application. Along with this use of fluoride in form of fluoridated toothpaste and mouth rinses are also advised.[23]

There is evidence for both fluoride gel and fluoride varnish as the professional application in the management of radiation decay in oral cancer patients. Fluoride varnish requires a more strict post-application routine as compared to the gel application. While fluoride gel application has practical issues like inducing a gag reflex.[24]

To the best of our understanding, there is no randomized clinical trial, stating which type of fluoride application is better for oral cancer patients. We aim to also analyze these two forms of professional fluoride applications in our population.

1.4 Oral Health-related quality of life (OHRQOL)

The overall level of home oral care and awareness is low to negligible in our population. A structural, economic, and easy-to-follow oral care program is essential for good quality of life in patients with head and neck carcinoma. Treatment of oral cancer primarily includes surgery, radiotherapy, and chemotherapy either as a separate modality or in a combination. The supportive treatment is rarely addressed due to constraints of economics and lack of integrated supportive care as part of a standard cancer treatment protocol. Quality of life is now considered the benchmark of treatment evaluation globally, apart from being one of the goals of treatment. Only disease-free survival is now not considered a valid success of treatment rather a disease-free survival with good quality of life is becoming the goal of treatment in this time of patient-centric holistic care. While in the context of cancer care and treatment now "It is the time of not just adding years in life, but adding life in the years". Inclusion of oral supportive care increases the quality of life in oral cancer patients.[25, 26]

Supportive care for oral cancer includes rehabilitation and restoration of the oro-dental health of the patient. This includes making the patient achieve effective mastication, swallowing, speech, and oral and facial esthetics in an optimal manner. This is the standard of care in the western population, but in India supportive care is introduced only when the known side effects of cancer treatment are presented. This results in a very poor quality of life in these patients, even when their cancer is cured.

Economics also plays a major role in compliance with oral care for our population. We would also be assessing the economical burden oral care puts on overall expenses in cancer treatment.

1.5 Aims, Objectives, and Hypothesis

1.5.1 Aim:

To compare two fluoride application regimens' impact on DMFT score in patients with oral cancer.

1.5.2 Primary objective:

To compare the impact of fluoride application regime of monthly versus quarterly application with either varnish form or gel form on DMFT index among oral cancer patients.

1.5.3 Secondary objective:

To standardize supportive oral care protocol (SOCP) and document the effectiveness of fluoride on quality of life among oral cancer patients.

1.5.4 Hypothesis:H0

There are no differences in terms of outcome for DMFT scores between the four intervention arms for oral cancer patients who had been irradiated in the region of the oral cavity.