ASSESSMENT OF EFFECTIVENESS OF BASTI, NASYA, MUKHOPAKRAMA, SHIRODHARA AND KARNAPURANA ON QUALITY OF LIFE OF ORAL CAVITY CANCER PATIENTS

A Thesis

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By

VD. SUSHRUT SADANAND SARDESHMUKH

M.D. (Kayachikitsa)

(PRN-05614007298)

Under the Guidance of

PROF (DR) VINEETA V. DESHMUKH

M.D. (Ayurved), Ph.D.

DEPARTMENT OF AYURVED

TILAK MAHARASHTRA VIDYAPEETH, PUNE

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CERTIFICATE OF THE SUPERVISOR

It is certified that work entitled **"Assessment of effectiveness of Basti, Nasya, Mukhopakrama, Shirodhara and Karnapurana on Quality of Life of Oral Cavity Cancer patients"** is an original research work done by **Vd. Sushrut S Sardeshmukh** under my supervision for the degree of Doctor of Philosophy in "**KAYA CHIKITSA**" to be awarded by Tilak Maharashtra Vidyapeeth, Pune.

To best of my knowledge this thesis embodies the work of candidate himself and has duly been completed. It fulfills the requirement of the ordinance related to Ph. D. degree of the TMV and is up to the standard in respect of both content and language for being referred to the examiner.

Date :

Place : Pune

Signature of the Supervisor

Prof (Dr) Vineeta V. Deshmukh

M.D. (Ayurved), Ph.D.

TILAK MAHARASHTRA VIDYAPEETH, PUNE

UNDERTAKING

I, **Vd. Sushrut S Sardeshmukh** is the Ph. D Scholar of the Tilak Maharashtra Vidyapeeth in **KAYA CHIKITSA** subject. The thesis entitled **"Assessment of effectiveness of Basti, Nasya, Mukhopakrama, Shirodhara and Karnapurana on Quality of Life of Oral Cavity Cancer patients"** under the supervision of **Prof (Dr) Vineeta V Deshmukh**, solemnly affirm that the thesis submitted by me is my own work. I have not copied it from any source. I have gone through extensive review of literature of the related published / unpublished research works and the use of such references made has been acknowledged in my thesis. The title and the content of research is original. I understand that, in case of any complaint especially plagiarism, regarding my Ph.D. research from any party, I have to go through the enquiry procedure as decided by the Vidyapeeth at any point of time. I understand that, if my Ph.D. thesis (or part of it) is found duplicate at any point of time, my research degree will be withdrawn and in such circumstances, I will be solely responsible and liable for any consequences arises thereby. I will not hold the TMV, Pune responsible and liable in any case.

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Vd. Sushrut S. Sardeshmukh
M.D. (Kayachikitsa)

Address: BSDT, Vishwashanti Dham,
Kesnand Road, Wagholi, Pune - 412207

Date:

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गुरुर्ब्रह्मा ग्रुरुर्विष्णुः गुरुर्देवो महेश्वरः ।

गुरुः साक्षात् परं ब्रह्म तस्मै श्री गुरवे नमः ।।

Sincere respects and prayers at the Holy Lotus feet of Lord Dhanwantari, Sadguru Shri. Sayajinath Mali Maharaj, Sadguru Shri. Marutinath Mali Maharaj, Shri. Swami Samartha Maharaj-Akkalkot, Shri. Shankarbaba Maharaj-Pune and Sadguru Shri. Prabhakar Sardeshmukh Maharaj-Wagholi.

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Vd. Sushrut Sadanand Sardeshmukh
Research Scholar

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INTRODUCTION

Cancer is known as one of the most dreaded diseases globally as well as in India. It is an abnormal growth of cells, proliferating and metastasizing in uncontrolled way. According to WHO, cancer is the second leading cause of death globally. In 2018, cancer is responsible for an estimated 9.6 million deaths. Globally, about 1 in 6 deaths is due to cancer[1]. According to GLOBOCAN 2018 there were about 18.1 million new cancer cases (17.0 million excluding non-melanoma skin cancer) and 9.6 million cancer deaths (9.5 million excluding non-melanoma skin cancers) in 2018.

Fig. 1 : Worldwide incidence of cancer by Globocan 2018

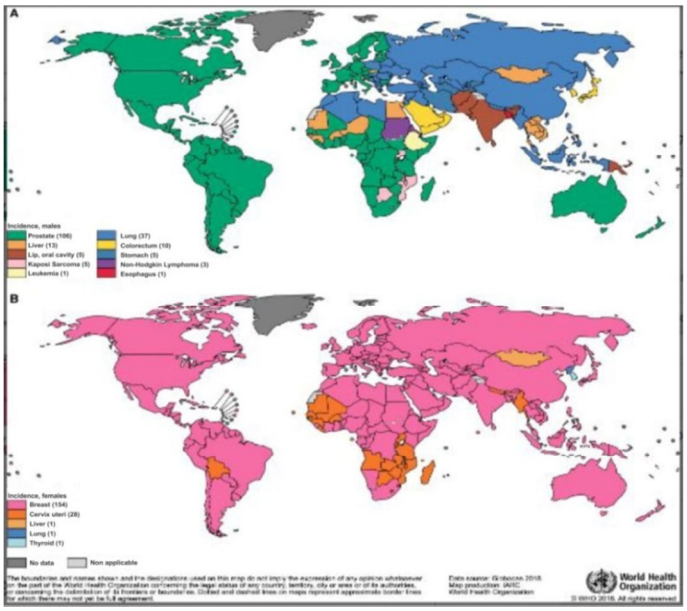


Fig. 2 : Worldwide mortality of cancer by Globocan 2018

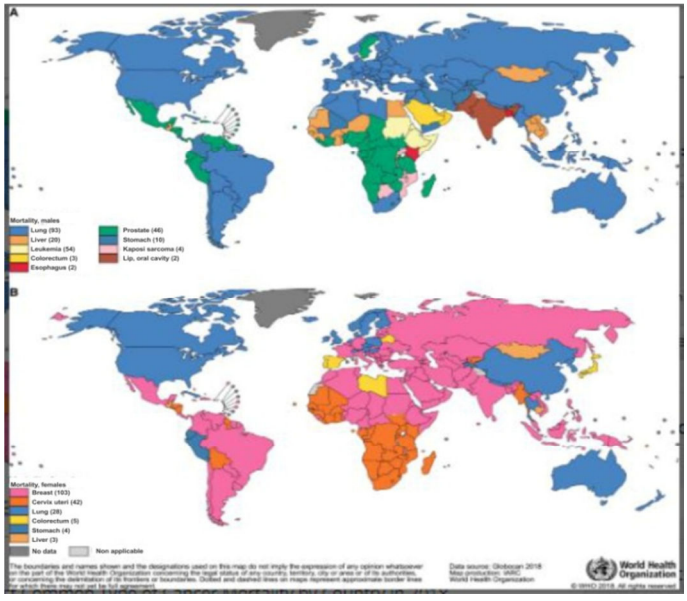


Fig 3: Number of new cases in India

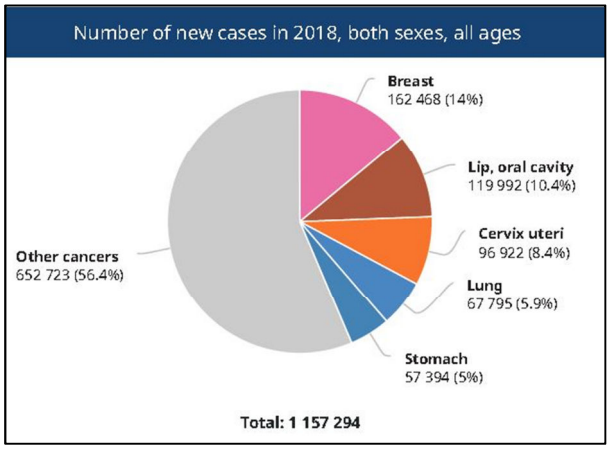


Fig. 4:

Number of new cases in 2018, males, all ages

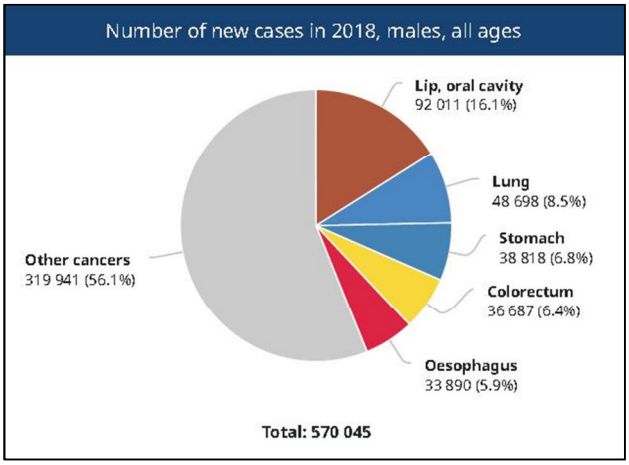
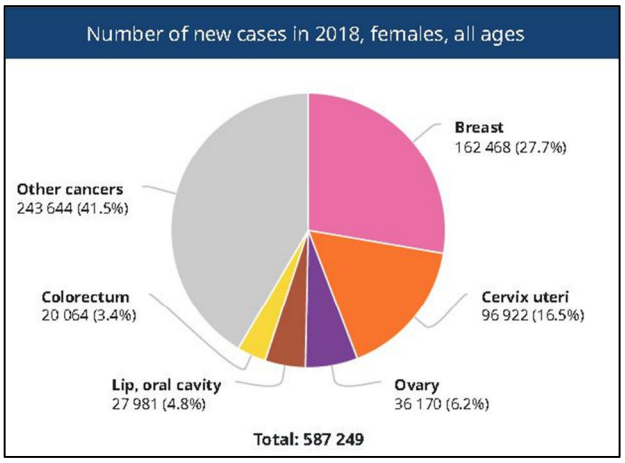


Fig. 5:

Number of new cases in 2018, females, all ages



Oral cavity cancers (OCCs) are the cancers occurring in various sites of oral cavity (from the lips up-to the tonsils) or oropharynx. They are placed within the top 10 ranking incidence of cancers globally and despite the progress in research and therapy, survival has not improved significantly in the past few years, representing a continuing challenge for biomedical science[2]. Oral cavity cancers rank second in India as per Globocan 2018[3]. Its prevalence is found to be higher in men comparatively than women[4]. The incidence rate of oral cavity cancer is seen more in low-income groups in India due to various addictions like tobacco chewing etc. There is also a delay in diagnosis of oral cavity cancer due to lack of knowledge[4]. The overall 5-year survival rate for oral cavity cancers patients is 52.0%. According to site of tumor, this rate is 71.4% for lip cancer, 56.3% for oral tongue cancer, and 42.7% for other parts of the oral cavity[5]**.** The death rate associated with this cancer is particularly high due to late diagnosis of cancer.

Oral cavity cancer includes a wide array of variations in histology of the oral cavity viz squamous cell carcinoma, sarcomas, lymphomas and mucosal melanomas, etc. Similar epidemiology, etio-pathogenesis and treatments are found in the all these types. Amongst the various types of OCC, the predominant histology seen is the squamous cell carcinoma[6].

We can see that in today's world of technology and science, it is a fast paced life. People are striving hard to complete their goals. Globalization has opened new opportunities and brought the world closer. But with these advances, the lifestyle of people has mostly become sedentary. The food habits have changed. The present trend of online food delivery apps has made a sharp rise in the irregular food habits and timings. Lack of exercise or irregular timings of exercise are also seen on a large scale. Online entertainment and phone entertainment has lead to staying awake till late night and lack of sleep and rest. Most of the populations presently have improper dietary habits and lifestyle. More over there is lack of information about personal hygiene including the Oral hygiene. There is very less awareness about the screening of oral cavity cancers and other cancers which result in delayed diagnosis and complications of cancer.

Various types of addictions are also on a rise. With the ultra modern and luxurious lifestyle trends being promoted, addictions like cigarette smoking, cigars, betel quid, gutka, alcohol, etc. are having a high rise among men as well as women. These are the main causative factors for oral cavity cancers. In 90 % of cases of OCCs, smoking and alcohol are considered as major risk factors[7]. Other factors include sharp teeth, ill fitting dentures, HPV infection, weak immune system, etc. The most common symptoms are a persistent sore or ulcer in the mouth or face which does not heal, development of white, red or mixed patches on tongue, gums or inner linings of mouth, difficulty in opening mouth, a lump or hard mass in the neck, difficulty in chewing or swallowing, unexplained weight loss, etc[8].

Oral cavity cancers are often diagnosed at a later time when it has metastasis. Most often the metastasis is found in the lymph nodes of the neck. The recovery is better when it is diagnosed locally in oral cavity than that of the metastasis. Till the time the cancer

metastasizes, at these later stages, there is a possibility that primary tumor has already invaded deep into local structures[10].

Oral cavity cancers generally are unnoticed by the patient at an early stage which makes them fatal. They are often without much pain or symptoms in initial stage and hence difficult to notice by the patient. The surrounding lymph nodes are always a high risk of metastasis thus the patient has more chances of loco-regional recurrence[10].

Different treatments may be used either alone or in combination, depending on the stage and location of the tumor. In general, surgery is the first treatment for cancers of the oral cavity, and may be followed by radiation or combined chemotherapy and radiation[9]. Oral cancers itself as a disease as well as its conventional treatments have their known side effects which mainly interferes with the esthetic and functional aspects of the patient. Complications like impaired masticatory function, ulceration and inflammation of the oral cavity hamper the chewing and speaking abilities. Xerostomia, trismus, stomatitis, dysphagia, etc. are commonly seen. These mainly result in altered nutrition of the patient leading to debility. Sensory functions related to the oral cavity are also affected[11].

Along-with the physical aspect, the psychological aspect of the patient also gets affected. The patient firstly gets a mental trauma after being diagnosed with cancer. The deformity of face along-with disrupted speech, debility lowers the patient's confidence levels. The lengthy period of treatments as well as the high investigations and treatment costs involved may affect the patient's tolerance and psychology. In-spite of the recent advances in diagnostics and treatment in oral cavity cancer, the recovery and survival rate has not been much encouraging. Similarly, the Quality of Life of the oral cavity cancer patients gets affected which may make the patient's life miserable.

Ayurveda is an ancient Indian medical science having its own distinct principles. It primarily aims on maintaining the healthy status in an individual and also has treatments described for various disorders. Healthy status according to Ayurveda includes physical as well as psychological well being. This classical medicine that has existed for thousands of years from the time of Vedas, has described many herbs, formulations and treatment

modalities which not only useful for the treatment but also promote good health and longevity without any side-effects to mankind.

Cancer, as a disease has not been mentioned in Ayurvedic Samhita. Various diseases and conditions mentioned in Ayurvedic texts like Dushta Vrana, Dushta Granthi, Dushta Arbuda, Dushta Vranashotha, Dushta Nadivrana, Dushta Visarpa show similarity with that of cancer.

In Ayurveda, the treatment principles comprise of Shamana Chikitsa, Shodhana Chikitsa and Rasayana Chikitsa. Shamana includes oral administration of Ayurvedic herbs or herbo-mineral combinations mainly useful for balancing the humors (Tridoshas) and reducing the toxicity in the body. Rasayana mainly deals with immuno-boosting drugs helpful in prevention of disease. Shodhana Chikitsa mainly deals with elimination of toxins from the body and helps to purify tissues ata deeper level. It is included in Panchakarma –viz. Vamana, Virechana, Basti, Nasya and Rakta Mokshana.

Vitiation of the Tridosha with predominance of Vata dosha is seen in cancer patients due various reasons related to the etiological factors to the conventional treatments. There are limitations for administration of Shamana Chikitsa alone and at times Shodhana procedures may also be needed. The Shodhana Chikitsa includes pre procedures, main procedures and post procedures. Snehana (Oleation) and Swedana (steam fomentation) reduce the vitiated Vata and induce Snigdhata resulting in relaxation and rejuvenation promoting the strength in the patient. Swedana helps in reducing the stiffness and also liquefies the toxins preparing them for the elimination process to follow. The main procedures of Shodhana help the body to get rid of the unnecessary toxins and the post procedures are mainly stabilizing for the body and functions to be normal. These cumulatively help in relieving the symptoms of oral cavity cancer and also counteract the side effects of conventional treatments viz. radiotherapy and chemotherapy. This systematic and scientific method of cleansing and purification helps for a faster recovery and mainly minimize the risk of recurrence which is a matter of concern.

Selection of Topic :

Many cancer patients of various types of cancers are treated at the Integrated Cancer Treatment and Research Center with an integrated approach. The Ayurvedic treatments rendered in case of oral cavity cancers included Shamana Chikitsa and Shodhana Chikitsa like Basti, Nasya along-with allied procedures like Gandusha, Mukhopakrama, Shirodhara and Karnapurana. Addition of Shodhana Chikitsa along with allied procedures showed significant relief insymptoms and also helped in reducing the side effects of the conventional treatments resulting in improvement of the Quality of Life of the patient. Based on this clinical experience, a case control study was designed to assess efficacy of Basti, Nasya, Gandusha, Mukhopakrama, Shirodhara and Karnapurana in patients of oral cavity cancer.

Ayurvedic treatment mainly in the form of Basti, Nasya along-with some allied procedures like Mukhopakrama, Shirodhara and Karnapurana can be found to be effective in oral cavity cancers especially in promoting a good quality of life and managing the side effects of radiotherapy. Basti can be helpful for Anulomana and thus controlling growth of tumor; Nasya as a treatment for vitiated Vata and Kapha Dosha can be helpful for relieving trismus, xerostomia and dysphagia; Mukhopakrama in the form of Gandusha and Mukhapratisarana for treating local disease and Karnapurana as a treatment for vitiated Vata Dosha and Shirodhara as a mind- body relaxing treatment. Various causative factors of Cancer as well as the conventional treatments tend to vitiate the Vata Dosha, Pitta Dosha and Kapha Dosha which aggravate and affect the various Dhatus and Mala. The Shodhana Chikitsa and other procedures from Ayurvedic treatments mentioned above help to pacify these vitiated Doshas, reduce the untoward effects of Cancer and its conventional treatments and promote better Quality of Life in patients of oral cavity cancer.

AIM :

To improve Quality of Life (QoL) of oral cavity cancer patients with Basti, Nasya, Mukhopakrama, Shirodhara and Karnapurana.

OBJECTIVES :

1. To assess efficacy of Basti, Nasya, Mukhopakrama, Shirodhara and Karnapurana on symptoms of oral cavity cancers and side-effects of radiotherapy.
2. To assess effectiveness of Basti, Nasya, Mukhopakrama, Shirodhara and Karnapurana on disease status.

LITERATURE REVIEW

A) LITERATURE REVIEW OF CANCER FROM MODERN MEDICINE PERSPECTIVE

A-I) CANCER :

Cancer is an abnormality found in the body. The human body is made up various components viz. systems, organs and cells. There are trillions of cells in a human body having various sites, structure and functions. A cell is a micro structure of the human body having its own components. There are different processes like the formation of cells, existence and destruction that takes place in a human body. This process in the normal physiological state helps to maintain the healthy status in a human being. If there happens to be a pathogenesis, this normal functioning is hampered giving rise to various disorders and diseases. Cancer is an abnormality of the cell, which is the basic unit of life in a human being. In cancer, there is an uncontrolled and abnormal growth of cells. There is a systematic and orderly process in cells in a healthy status. A change in this orderly process causes cancer. It begins with the genetic changes that affect the orderly process of cells. An uncontrolled growth of cells results in a mass or tumor[12].

Cancer is a complex disease predominantly genetic which involves various genetic changes. It's a collection of diseases which occurs due to initial mutation even in a single cell from any of the various cells in the multiple cell regulatory system. If it is affected further by mutation, it causes the initiated cell to proliferate and still additional mutations in cells with grown advantage, invasive and metastatic properties. The genetic alterations include activation of proto-oncogenes and inactivation of tumor suppressor genes. It can remain in a dormant stage for any length of period. Cancer is characterized by invasion in the normal tissue and metastasis at distant organs. The metastatic cells have different biochemical and immunological properties conducive of the spread of the disease [13].

Cancerous tumors are malignant, which means they can spread into, or invade, nearby tissues. In addition, as these tumors grow, some cancer cells can break off and travel to distant places in the body through the blood or the lymph system and form new tumors far from the original tumor.

Unlike malignant tumors, benign tumors do not spread into, or invade, nearby tissues. Benign tumors can sometimes be quite large, however. When removed, they usually don't grow back, whereas malignant tumors sometimes do. Unlike most benign tumors elsewhere in the body, benign brain tumors can be life threatening[14].

A II) ORAL CAVITY CANCER:

a. ANATOMY OF ORGANS OF ORAL CAVITY:

The oral cavity begins at the border between the skin and the lips (vermillion border).The roof of the mouth is formed by the hard palate. The oral cavity leads into the oropharynx, which includes the soft palate, the back of the tongue and the tonsils. The inner surface of the cheeks forms the sides of the oral cavity. The lowest part of the oral cavity is the floor of the mouth, which is covered by the tongue[15].

The different parts of oral cavity include[16]:

- Lips
- Labial mucosa (inner lining of the lips)
- Commissure of lips (where the upper and lower lips meet at the corner of the mouth)
- Vestibule (a space bounded by the teeth and gums on the inside and the mucosal
- Surface of the lips and cheeks on the outside)
- Oral tongue (the front two-thirds of the tongue)
- Floor of the mouth
- Buccalmucosa (the inner lining of cheeks)
- Gingiva (gums)
- Retro molar trigone (the area just behind the back molars in the lower jaw)
- Hard palate (the bony part at the front of the roof of the mouth)
- Teeth
- Lower jaw (mandible)
- Upper jaw (maxilla)

Fig.6 : Anatomy of oral cavity

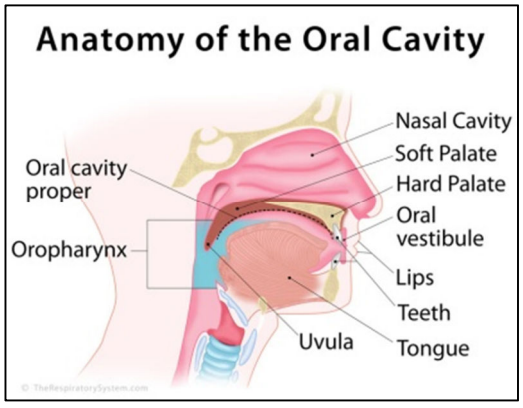
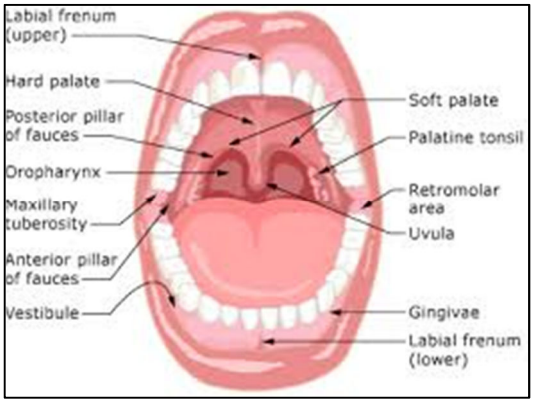


Fig. 7 : Anatomy of oral cavity



b. FUNCTIONS OF ORGANS OF ORAL CAVITY[17]:

i. Functions in the Digestive System:

It is where the first step of digestion – ingestion or food intake – takes place. The oral cavity is the primary external opening leading into the gastrointestinal or digestive tract. As you eat, the teeth tears, breaks, and grinds the food (the process medically known as mastication), while the tongue contributes to prepare it into a soft mass to be digested by mixing it with saliva (secreted by the salivary glands), completing the mechanical digestion of food. The taste buds located on the tongue also allows you to taste the food.

The process of chemical digestion begins within the oral cavity as well, with the salivary glands also secreting certain enzymes to break down starch and carbohydrates.

ii. Role in Speech Production:

The mouth is instrumental in speech production, as the air exiting through the Oral cavity from the voice box is manipulated here to form words. The lips, tongue, hard and soft palates, and even the teeth are vital in speaking, as well as any other sound production. Even a minor malformation or abnormality in the development or functioning of the oral cavity can seriously affect an individual's daily life and activities, as it allows humans to eat, breath, speak, and express.

iii. Role in Respiratory System:

Though not a primary part of the human respiratory system, its functions include serving as the secondary passage for air to enter and exit the respiratory tract during inhalation and exhalation. So, when the nasal cavity cannot function properly, like in case of a blocked nose, the oral cavity serves as the pathway for air, and leads it into the airways through the pharynx. However, since the oral cavity is much shorter than the nasal cavity, and lacks the mucus lining and cilia present in the latter, it does not moisten and purify the inhaled air

c. HISTOLOGY OF ORAL CAVITY CANCER:

Cancer has been differentiated in types which are based on its occurrence site.
The four main types of Cancer are[18]-

- **Carcinomas:** A carcinoma begins in the skin or the tissue that covers the surface of internal organs and glands. Carcinomas usually form solid tumors. They are the most common types of cancers are breast cancer, lung cancer, prostate cancer and colorectal cancer.

- **Sarcomas:** A sarcoma begins in the tissues that support and connect the body. A sarcoma can develop in fat, muscles, nerves, tendons, joints, blood vessels, lymph vessels, cartilage, or bone.

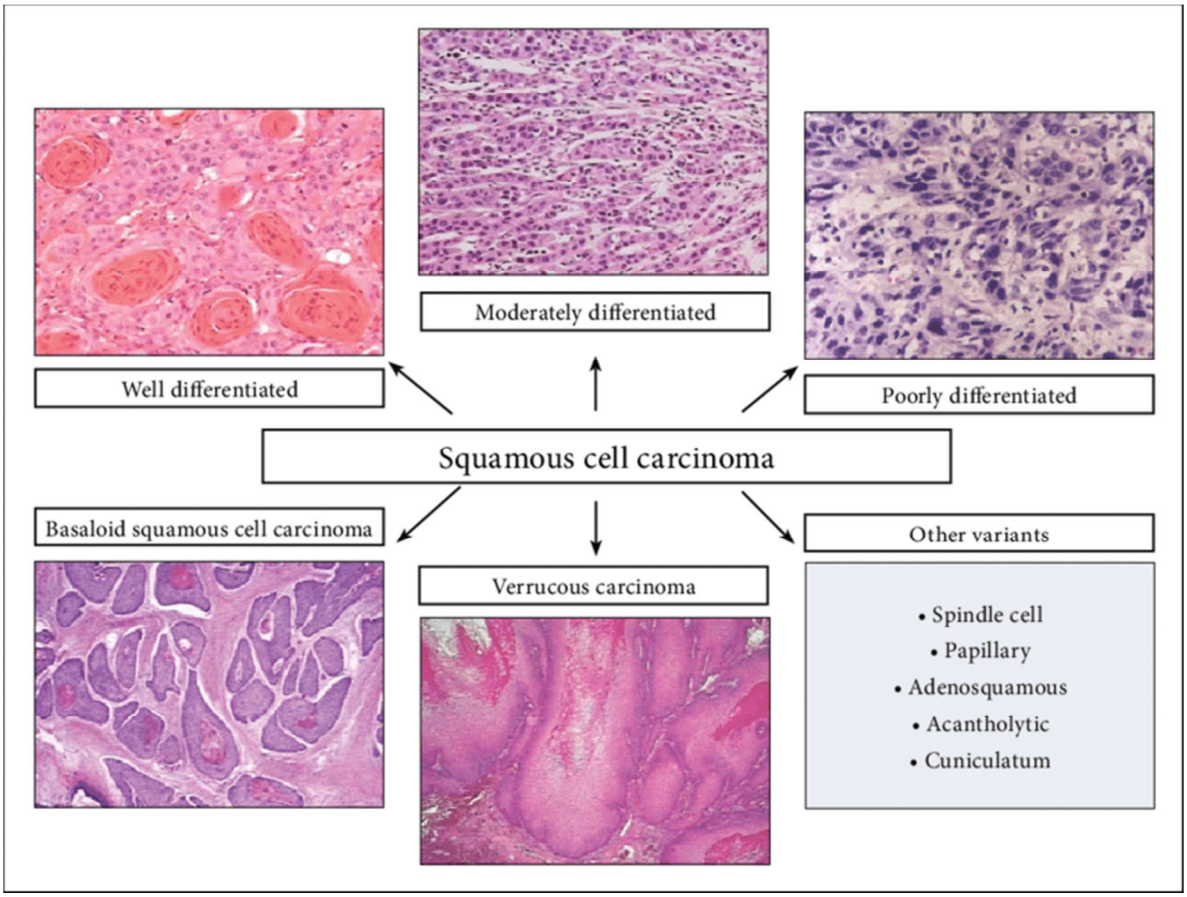
- **Leukemias:** Leukemia is a cancer of the blood. Leukemia begins when healthy blood cells change and grow uncontrollably. The four main types of leukemia are acute lymphocytic leukemia, chronic lymphocytic leukemia, acute myeloid leukemia, and chronic myeloid leukemia.

- **Lymphomas:** Lymphoma is a cancer that begins in the lymphatic system. The lymphatic system is a network of vessels and glands that help fight infection. There are two main types of lymphomas: Hodgkin lymphoma and Non-Hodgkin lymphoma.

Amongst all the malignant neoplasms that arise from the Head and Neck, the most commonly seen are squamous cell carcinoma (SCC) which arise from the surface epithelium. Lympho-epithelioma, spindle cell carcinoma, verrucous carcinoma and undifferentiated carcinoma are its other variant. Lymphomas and wide variety of other malignant and benign neoplasms makeup the remaining cases[19].

Oral squamous cell carcinoma (OSCC) occurs as a result of various processes which involves genetic mutations and chromosomal abnormalities[20]. Clinically, it often presents as an ulcerated lesion with a central necrotic area and rolled up margins[21]. Stratified squamous epithelial lining of the buccal mucosa, tongue, floor of the mouth, palate and lip are the common sites for OSCC.

Fig. 8 : Types of Squamous cell carcinoma



d. ORAL CAVITY CANCER -RISK FACTORS:

A risk factor is anything that increases the chance of developing a disease or infection. Oral cavity cancer is caused due to various factors which are broadly classified as epigenetic and genetic[22].

1. **Epigenetic factors :** These mainly includes addictions like tobacco, alcohol, betel quid, diet and nutrition and mouth wash. Other associated factors include environmental factors like viral infections, fungal infections; immune-suppression due to occupational risks, dental factors, syphilis and radiation.
2. **Genetic factors :** This include genetic mutations. For examples genetic syndromes like Fanconi anemia and dyskeratosis congenital are high risk for developing oral cavity cancers.

Of all the above mentioned factors, addictions of tobacco and alcohol are widely considered to be its major risk factors.

i. **Tobacco** : Tobacco consumption is still the most important risk factor for cancer. various Tobacco addiction can be seen broadly as smokeless and smoking[23].

- **Smokeless Tobacco :** Tobacco when not taken in a burnt form is known as smokeless tobacco. It can be seen in various forms like chewing tobacco, dip, snuff, etc.
- **Chewing Tobacco :** The typical manner in which tobacco is chewed is by placing the dry and crushed leaves between the cheek and lower lip and swallowing as the saliva mixes with it. This is followed by spitting the remaining tobacco from mouth. This exposes the skin and surface of the mouth lining to tobacco.
- **Snuff :** It is of two types viz. wet or moist snuff for oral consumption and dry snuff for snoozing i.e snuff is inhaled through the nose. Usually a pinch of moist snuff is placed between the cheek and the gum or behind the upper and lower lip. The habit of oral snuff can cause snuff dipper cancer or verrucous carcinoma.
- **Smoking Tobacco :** Tobacco smoke from cigarettes, cigars and pipes may cause oral cavity cancers.

- **Cigarettes :** The number of cigarettes consumed relates to the risk of death in patients of OCC. It has been found through numerous studies studying the relative risk for oral cavity cancer amongst former smokers is found that risk was lower in people who smoked for few years than the former smokers who continued to smoke later too. It is found that if there is a smoking abstinence of 3 to 5 years, it decreases the risk of oral cancer by 50 %[24].
- **Cigars and Pipes :** These are indirect sources of tobacco which also show increased risk for oral cancers. In a comparative analysis done in a prospective and retrospective studies mention that the mortality rate for cigar and pipe smokers is either similar or higher than the risk found in cigarette smokers[25].

ii. **Alcohol :** Alcohol consumption has shown to act synergistically with tobacco in the increased risk of development of oral cavity cancers. Significant study has been done to analyze in patients who drink alcohol but are non-smokers and patients who smoke but are non-drinkers. It has been found that alcohol can be an independent risk factor for oral leucoplakia. Alcohol is also shown to increase the permeability of oral mucosa producing alteration in the morphology which is seen as epithelial atrophy resulting easier penetration of the carcinogens in oral mucosa[26,27].

iii. **Betel Quid and Gutka :** Betel quid commonly known as Paan, usually contain betel leaves, tobacco, areca nut, slake lime, etc can often be combined with various spices. Common forms are mishri (burnt tobacco), khaini (tobacco and lime), zarda (boiled tobacco), mava (tobacco, lime and areca nut) and gadakhu (tobacco and molasses). Studies have shown that betel quid and especially tobacco and areca nut are carcinogenic, mutagenic and have genotoxic potential. They can cause oral cavity cancers and conditions like leucoplakia, erythroplakia and oral sub mucus fibrosis[28].

iv. **Diet and Nutrition :** Food items nowadays contain excessive use of toxic fertilizers and pesticides. It has found that various dietary products available in the market contain artificial flavours and colours which are also harmful. Pesticides are potentially toxic to humans and can have acute as well as chronic health effects depending on the quantity and ways of exposure. When people come into contact with large quantities of pesticide, this may cause acute poisoning or long-term health effects, including cancer and adverse effects on reproduction[29]. A comprehensive report, “Food Dyes: A Rainbow of Risks” published by The Center for Science in the Public Interest (CSPI) details the inherent risks of nine different dyes widely used in

common foods. The report reveals that common food dyes pose risks of cancer, hyperactivity in children, and allergies[30]. Several studies have linked increased cancer risk and mortality with low intake of fruits and vegetables which are good sources of beta carotenes[31].

v. **Mouth wash :** There are some assumptions about mouthwashes being a cause for oral cancer. This is mainly due to the alcohol content and more frequency of usage by consumers. The association of mouthwash and oral cancers is yet not clearly established however it showed to be significant with high frequency of use viz. thrice a day for a prolonged period of time in some cases[32].

vi. **Viral infections :** Viral infections have shown to affect and interfere the host's cell cycle mechanism and is usually responsible for malignancy. Predominant viruses related in oral cancer causes are Human Papilloma Virus (HPV), Epstein – Barr virus (EBV) and Herpes simplex virus. Among these, HPV are the most common viruses in oral carcinogenesis. They are double stranded DNA viruses and are epithelio-tropic. Some of them are referred to as high risk types which are associated with OSCC and oral pre-malignant lesions. The mode of transmission is between the epithelial cells caused mainly through sexual contact which involves conventional as well as oral. The moist epithelial (squamous cells) surfaces include areas covered by skin, mucosa viz. oral cavity, throat, tongue, cervix, vulva, vagina, penis and anus[33,34].

vii. **Dental factors** : Improper fitting dentures, sharp / broken teeth, poor oral hygiene and chronic ulceration due to the above mentioned reasons may promote neoplasm in the presence of other risk factors. Dental factors influence for oral cancer development has yet not been established with evidence[35].

viii. **Radiation :** The use of chemicals as well as other sources of pollution are a big threat to the vital and protective layer like ozone. Actinic radiation like other harmful radiations from the direct and intense sunlight is known to produce cancer along vermilion border of the lips. These types of cancers are more common in the fair skinned individuals who are exposed more to sunlight. It is seen that the dark pigment in skin protects the skin against actinic radiation damage[36].

e. ORAL CAVITY CANCER- SCREENING FOR EARLY DETECTION :

Screening of cancer plays a very important role as it's the stage where a person comes to know whether there is a cancer in the body or even at times a risk of having cancer later. Generally a patient approaches for screening only after he / she experiences some symptoms. Timely screening can help for an early detection which may be asymptomatic. A screening should preferably be acceptable by application, inexpensive and possible to conduct on a large number of patients[37].

Fig. 9 : Screening of oral cavity

As regards oral cavity cancer, there is no standard or routine screening test.

Screening for oral cavity cancer is mostly done during visit to the dentist for a routine check up or for any dental problems. The examination for oral cancers mainly focuses to find lesions in oral cavity, areas of leukoplakia (abnormal white patch of cells), erythroplakia (abnormal red patch of cells). The lesions of leukoplakia and erythroplakia on mucous membranes may be cancerous.

Certain procedures may be used for lesions of oral cavity to find any abnormal tissue that might later develop into oral cancer.

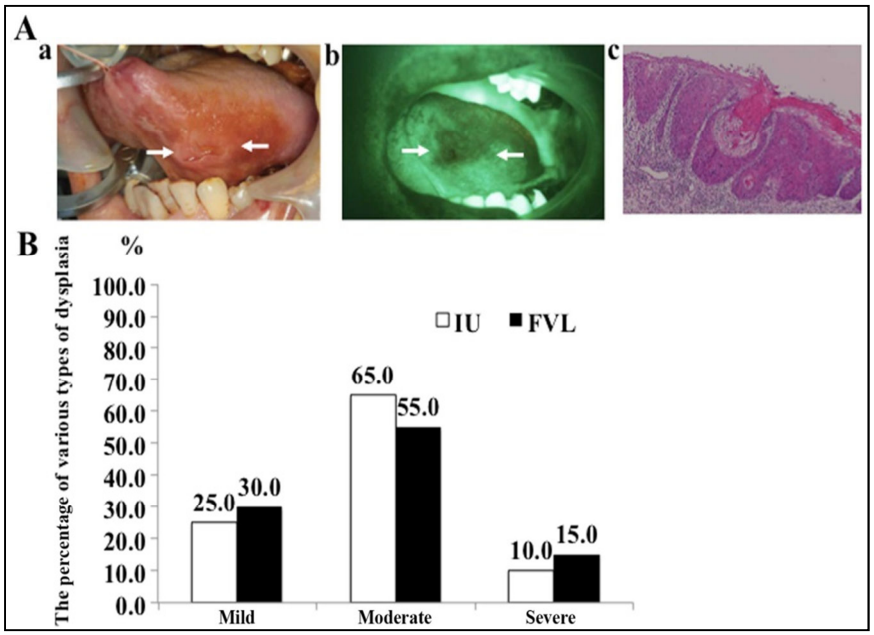
1. **Exfoliative cytology** :

   It is a procedure which involves collection of cells from the lip or oral cavity. A sterile bud or a piece of sterile cotton or a sterile brush can be used to gently scrape off cells from the lips, tongue, mouth or throat as sample which is later studied under a high definition microscope by a pathologist to find any abnormality if present[38].

2. **Fluorescence staining** :

   It's a procedure which involves the inspection of lesions in oral cavity using a special light. The patient is given a fluorescent mouth wash to rinse the mouth. This makes the normal tissue to look different that the abnormal tissue when seen under special light[39].

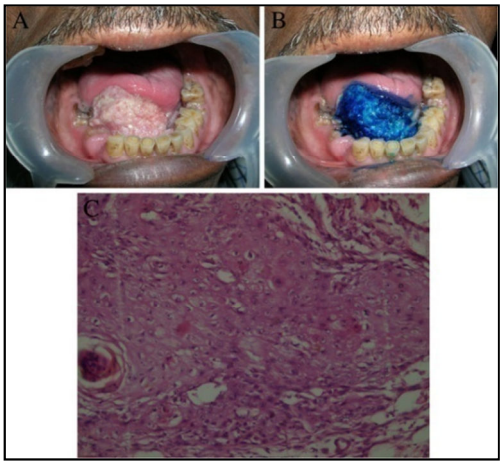
Fig. 10 : Fluorescence staining



3. **Toluidine blue stain** :

   This is a technique in which a special blue dye is used to coat the lesions in the oral cavity. After staining, the darker areas are the cancer affected areas or prone to cancer areas[40].

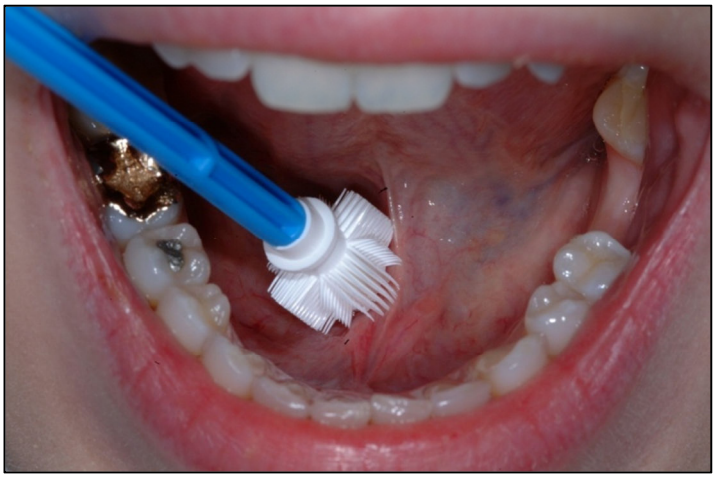
Fig. 11 : Toluidine blue stain



4. **Brush biopsy** :

   This technique includes using of a sterile brush to remove the cells from the oral cavity. The brush is specially designed to collect cells from all layers of a lesion. The collected cells are then studied under a high definition microscope to find any abnormality if there[41].

Fig. 12 : Brush biopsy



It is generally seen from the studies that more than half the cases of oral cancers spread to the surrounding lymph nodes or other areas before they are screened. It has not been confirmed yet that screening would reduce the risk of mortality in oral cavity cancers[42,43].

f. ORAL CAVITY CANCER - SIGNS AND SYMPTOMS :

The stage and primary site of tumor in a case of oral cavity cancer affects its manifestations. The following signs and symptoms are generally present in the carcinoma of oral cavity[44] –

1. A patch in the mouth which is rough and does not heal within two weeks
2. Small lump inside the inner lining of oral cavity
3. Erosions around lips and gums
4. Loosening of teeth and bad breathe
5. Decreased tongue mobility
6. Numbness, loss of feeling and sensation inside the oral cavity.
7. Loss of taste.
8. Severe weight loss
9. Difficulty in swallowing.
10. Alterations in speech.
11. Loss of appetite.
12. Lymphadenopathy in neck region
13. Trismus.

Fig. 13 : Oral cavity cancer symptoms

g. ORAL CAVITY CANCER – DIAGNOSIS :

The diagnosis methods in oral cancers are as follows[45] –

1. **History and physical examination** :

   A thorough head and neck examination by one or more physicians is useful as an initial evaluation.

   Any primary tumor, its location and extent along with any clinically positive cervical lymph node can be examined by this.

2. **CT Scan / MRI** :

   A contrast and enhanced CT scan and/or MRI is advised to almost all patients to understand the extent of local or metastasized disease. The scan is to be done before performing the biopsy in the patient so that the post biopsy changes are not confused with the tumor.

3. **Biopsy** :

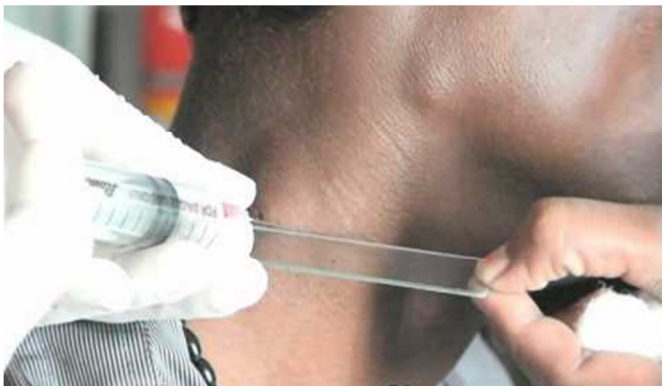
   During examination of oral cavity by the concerned doctor, if any abnormality is found or doubted, then a small tissue sample of that area called as biopsy is usually taken for assessment. This is generally done under local anesthesia.

Fig. 14 : Biopsy

4. **Fine needle aspiration cytology (FNAC) :**

This technique is used in patients presenting with a metastatic node from an unknown primary site. It is a type of minimal invasive technique of biopsy.

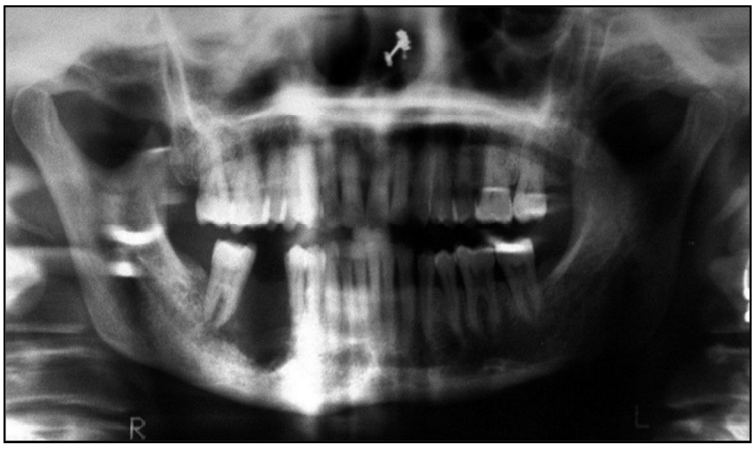
Fig. 15 : Fine needle aspiration cytology



5. **Ortho Pan Tomogram (OPG) :**

It is a dental imaging study and it gives a panoramic view of mouth and is helpful to give information about the teeth and bones of the upper and lower jaw. Also, if the lesion extends to lower GB sulcus or lower alveolus then an OPG or plain radiograph of mandible is done.

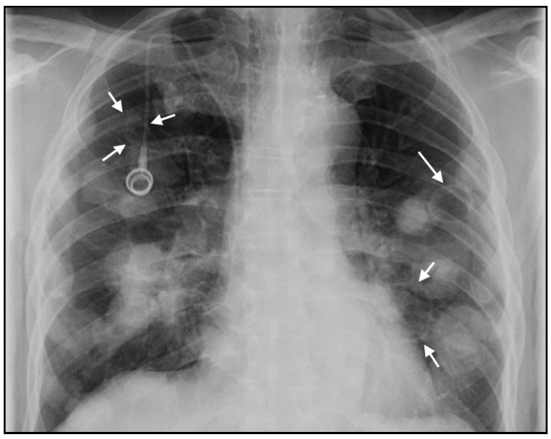
Fig. 16 : Ortho Pan Tomogram



6. **Chest Radiograph** :

   It is done to determine the presence of any distant metastasis.

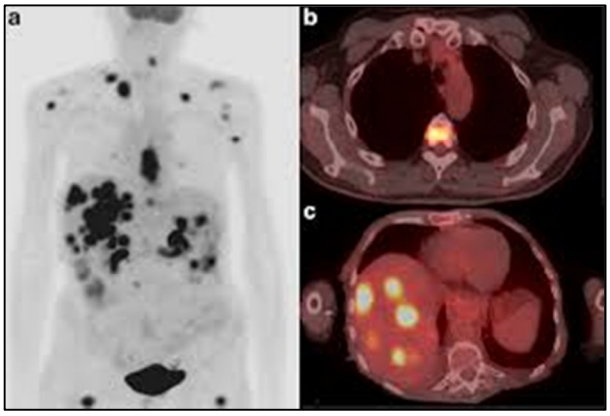
Fig. 17 : Chest Radiograph



7. **Positron emission tomography (PET)** :

   It is a diagnostic technique used to examine peripheral metastasis.

Fig. 18 : Positron emission tomography



8. **Different Lab investigations** like haemogram, liver function test, renal function test, etc. may also be useful in the diagnosis.

h. STAGES AND GRADES OF ORAL CAVITY CANCER :

TNM STAGING SYSTEM:

Method of staging oral carcinomas is referred as the TNM method and it is in accordance to AJCC Cancer Staging Manual 8th edition[46]. TNM staging is done according to the specific site and section of the oral cavity.

In this method,

'T' describes the tumour,

'N' describes the lymph nodes,

'M' describes distant metastasis.

1. **Time of Classification**

Table 1 : TNM Classification

Classification	Definition
cTNM or TNM	Clinical Classification: Used for all patients with cancer identified before treatment. It is composed of diagnostic workup information, until first treatment, including clinical history and symptoms, physical examination, imaging, endoscopy, biopsy of the primary site, biopsy or excision of a single regional node or sentinel nodes, or sampling of regional nodes, with clinical T, biopsy of distant metastatic site, surgical exploration without resection, and other relevant examinations
prTNM	Pathological Classification: Used for patients if surgery is the first definitive therapy. Composed of information from diagnostic workup from clinical staging combined with operative findings, and pathology review of resected surgical specimens
ycTNM	Post therapy Clinical Classification: After primary systemic and/or radiation therapy, or after neoadjuvant therapy and before planned surgery. Criteria: First therapy is systemic and/or radiation therapy
ypTNM	Post therapy Pathological Classification: Used for staging after neoadjuvant therapy and planned post neoadjuvant therapy surgery. Criteria: First therapy is systemic and/or radiation therapy and is followed by surgery.
rTNM	Recurrence or Re-treatment Classification: Used for assigning stage at time of recurrence or progression until treatment is initiated
aTNM	Autopsy Classification: Used for cancers not previously recognized that are found as an incidental finding at autopsy and not suspected before death (i.e., this classification does not apply if an autopsy is performed in a patient with a previously diagnosed cancer).

2. Definition of Primary Tumor (T)

Table 2 : Classification of Tumor

T Category	T Criteria
TX	Primary tumor cannot be assessed
Tis	Carcinoma in situ
T1	T1 Tumor < 2 cm with depth of invasion (DOI)* <= 5 mm
T2	Tumor ¢ 2 cm with DOI* > 5 mm or tumor > 2 cm and < 4 cm with DOI* < 10mm
T3	Tumor > 2 cm and = 4cm with DOI* > 10 mm or tumor > 4 cm with DOI* < 10 mm
T4	Moderately advanced or very advanced local disease
T4a	Moderately advanced local disease Tumor > 4cm with DOI* > 10 mm or tumor invades adjacent structures only (e.g., through cortical bone of the mandible or maxilla or involves the maxillary sinus or skin of the face) Note: Superficial erosion of bone/tooth socket (alone) by a gingival primary is not sufficient to classify a tumor as T4.
T4b	Very advanced local disease Tumor invades masticator space, pterygoid plates, or skull base and/or encases the internal carotid artery

*DOI is depth of invasion and not tumor thickness

3. **Definition of Regional Lymph Node (N)**

Table 3 : Lymph Node classification

cN Category	cN Criteria
NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in a single ipsilateral lymph node, 3 cm or smaller in greatest dimension and ENE(-)
N2	Metastasis in a single ipsilateral node larger than 3 cm but not larger than 6 cm in greatest dimension and ENE(-); or metastases in multiple ipsilateral lymph nodes, none larger than 6 cm in greatest dimension and ENE(-}; or in bilateral or contralateral lymph nodes, none larger than 6 cm in greatest dimension, ENE(-)
N2a	Metastasis in a single ipsilateral node larger than 3 cm but not larger than 6 cm in greatest dimension and ENE(-)
N2b	Metastases in multiple ipsilateral nodes, none larger than 6 cm in greatest dimension and ENE(-)
N2c	Metastases in bilateral or contralateral lymph nodes, none larger than 6 cm in greatest dimension and ENE(-)
N3	Metastasis in a lymph node larger than 6 cm in greatest dimension and ENE(-); or metastasis in any node(s) with clinically overt ENE(+)
N3a	Metastasis in a lymph node larger than 6 cm in greatest dimension and ENE(-)
N3b	Metastasis in any node(s) with clinically overt ENE(+)

4. Pathological N (pN)

Table 4 : Pathological Lymph Node classification

pN Category	pN Criteria
NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in a single ipsilateral lymph node, 3 cm or smaller in greatest dimension and ENE*(-}
N2	Metastasis in a single ipsilateral lymph node, 3 cm or smaller in greatest dimension and ENE(+); or larger than 3 cm but not larger than 6cm in greatest dimension and ENE(-); or metastases in multiple ipsilateral lymph nodes, none larger than 6 cm in greatest dimension and ENE(-); or in bilateral or contralateral lymph node(s), none larger than 6 cm in greatest dimension and ENE(-)
N2a	Metastasis in a single ipsilateral node 3 cm or less in greatest dimension and ENE(+); or a single ipsilateral node larger than 3 cm but not larger than 6 cm in greatest dimension and ENE({-)
N2b	Metastases in multiple ipsilateral nodes, none larger than 6 cm in greatest dimension and ENE(-)
N2c	Metastases in bilateral or contralateral lymph node(s), none larger than 6 cm in greatest dimension and ENE(-)
N3	Metastasis in a lymph node larger than 6 cm in greatest dimension and ENE(-};or metastasis in a single ipsilateral node larger than 3 cm in greatest dimension and ENE(+);or multiple ipsilateral, contralateral, or bilateral nodes any size and ENE(+) in any node; or a single contralateral node of any size and ENE(+)
N3a	Metastasis in a lymph node larger than 6 cm in greatest dimension and ENE(-)
N3b	Metastasis in a single ipsilateral node larger than 3 cm in greatest dimension and ENE(+);or multiple ipsilateral, contralateral, or bilateral nodes any size and ENE(+) in any node; or a single contralateral node of any size and ENE(+)

*ENE - extranodal extension

5. Definition of Distant Metastasis (M)

Table 5 : Metastasis

	M Category	M Criteria
	cM0	No distant metastasis
	cM1	Distant metastasis
	pM1	Distant metastasis, microscopically confirmed

6. AJCC Prognostic Stage Groups

Table 6 : Prognostic Stage Groups

	When T is ….	And N is ….	And M is….	Then the stage group is….
	Tis	NO	MO	0
	T1	NO	MO	I
	T2	NO	MO	II
	T3	NO	MO	III
	T1, T2, T3	N1	MO	III
	T4a	NO, N1	MO	IVA
	T1, T2, T3, T4a	N2	MO	IVA
	Any T	N3	MO	IVB
	T4b	Any N	MO	IVB
	Any T	Any N	M1	IVC

7 Histologic Grade (G)

Table 7 : Histologic Grade

	G	G Definition
	GX	Cannot be assessed
	G1	Well differentiated
	G2	Moderately differentiated
	G3	Poorly differentiated

8 Lymphovascular Invasion (LVI)

Table 8 : Lymphovascular Invasion

	Component of LVI coding	Description
	0	LVI not present (absent) / not identified
	1	LVI present / identified, NOS
	2	Lymphatic and small vessel invasion only (L)
	3	Venous (large vessel) invasion only (V)
	4	Both lymphatic and small vessel and venous (large vessel) invasion
	9	Presence of LVI unknown / indeterminate

i. ORAL CAVITY CANCER MANAGEMENT :

Different treatments may be used either alone or in combination, depending on the stage and location of the tumor. In general, surgery is the first treatment for cancers of the oral cavity, and may be followed by radiation or combined chemotherapy and radiation. Oropharyngeal cancers are usually treated with a combination of chemotherapy and radiation[47].

Health professionals associated with cancer care :

The team of experts, doctors involved in the treatment of oral cancers may include -

- Otolaryngologist (ENT doctor) : A surgeon to treat diseases of head and neck.
- Oral and Maxillofacial Surgeon : Surgeon to treat diseases of mouth, teeth and jaw.
- Radiation Oncologist : A doctor to treat the cancer with radiation therapy.
- Medical Oncologist : A doctor to treat the cancer with medicines like chemotherapy and targeted therapy.
- Other specialists like nurses, nutritionist, speech therapists, dentists, social workers and psychologists may also be involved for better care and treatment of the patient.

The role of experts is based on the stage and location of the tumor in the patient.

- **Treatment options for oral cavity cancer by stage–**

(Practice Guidelines for Buccal mucosa cancer (SCC) in India according to Indian Council of Medical Research Guidelines)[48]

The type of treatment depends on the stage of cancer and tumor site.

Table 9 : Stage and treatment planning

Stage (TNM)	**Initial treatment planning**
T1 N0 M0	Surgery or Radiotherapy (RT) (EBRT+ISI Boost)
T2 N0 M0	Surgery (Primary + SOHND or RT(EBRT+ISI boost)
T3/ T4a N1/N2 M0	Surgery followed by CT-RT (or RT) or Radical CT + RT.
T3/ T4 N1/N2 M0	Borderline Resectable Induction chemotherapy followed by surgery or CT + RT
T4B or N3(Fixed Node)	Chemotherapy /RT
Occult primary (SCC on biopsy)	Surgery or CT +RT
Recurrent disease < 6 months old	CT + RT if patient had undergone surgery earlier and surgery if CT + RT earlier
Recurrent disease > 6 months after initial treatment	Surgery if resectable / CT + RT if unresectable and RT Naïve
Recurrent disease advanced	Palliative chemotherapy or best supportive care.

- **Treatment decision in oral cancer** :

It's very important to have a detailed and overall discussion for treatment as a good plan of treatment is essential for better recovery and results. The treatment goals have to be discussed and also the possible side effects of the treatments involved should be considered. For a good treatment plan, considering the overall health of the patient, the type and stage of cancer, possible impact of treatment on various activities and functions of the patient is necessary.

In some cases, a second opinion is also advisable so as to have better information about the diagnosis and treatment modalities.

1. **Surgery for oral cavity cancer :**

Depending on the site and stage of the cancer, several types of operations can be used. Surgery is often the first choice of treatment in oral cancers and is preferred in the early stages, small lesions and when there is no metastasis. Many a times, a reconstructive surgery is recommended after the main surgery for cosmetic and convenience of activities of that region[49].

Commonly used techniques are-

- Tumor resection.
- Mohs micrographic surgery (for cancer of lips)
- Glossectomy (removal of tongue).
- Mandibulectomy (removal of jaw bone)
- Maxillectomy (removal of front part of roof of mouth).
- Robotic surgery.
- Laryngectomy.
- Neck dissection.

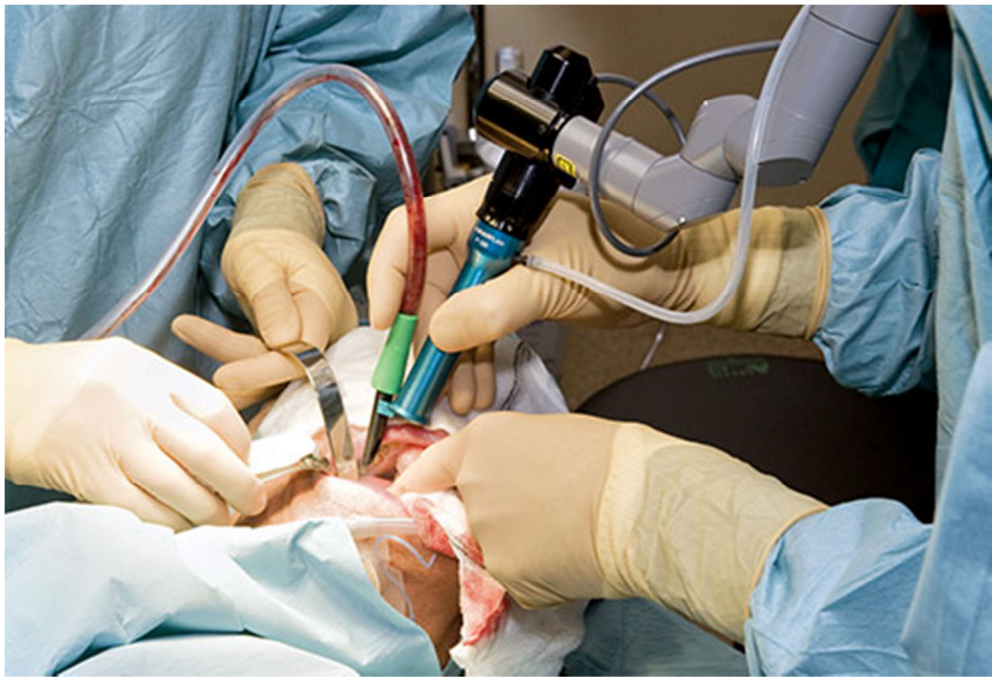
Surgeries to save or restore body functions –

- Tracheostomy.
- Feeding tube.
- Gastrostomy tube (G-tube).
- Percutaneous endoscopic gastrostomy (PEG tube).

- Nasogastric feeding tube (NG tube)
- Dental extraction and implants.

Surgery involves risk factors like blood clots, complications of anesthesia and pneumonia. The risk factor is higher in complex surgeries.

Fig. 19: Surgical treatment in cancer



2. Radiation therapy in oral cavity cancers:

It is a treatment modality in oral cavity cancers which uses high energy X-rays or particles to destroy the cancer cells or regress their proliferation rate. It is preferred in cancers with small lesions[50].

Radiation therapy (RT) is combined with surgery in larger cancers. Sometimes along with radiation therapy, adjuvant chemotherapy or targeted drug therapy is also given as therapeutic or also to shrink the larger tumors prior to surgery. It also makes the extensiveness of the surgery less and may involve less invasive surgery.

- **Types of Radiation therapy** :

  External Beam Radiation Therapy (EBRT) -

  This is the most common technique of radiation therapy where a beam of radiation is carefully focused from a machine to the patient's body. An exact dose calculation and an accurate aim of beam to the tumor site is done by the Radiation Oncologist to reduce the side effects. Treatment is usually given 5 days a week and upto 6 to 7 weeks.

  There are methods like hyperfractionation and accelerated fractionation which many times reduce the risk of local recurrence.

- **Side effects of Radiation therapy** :

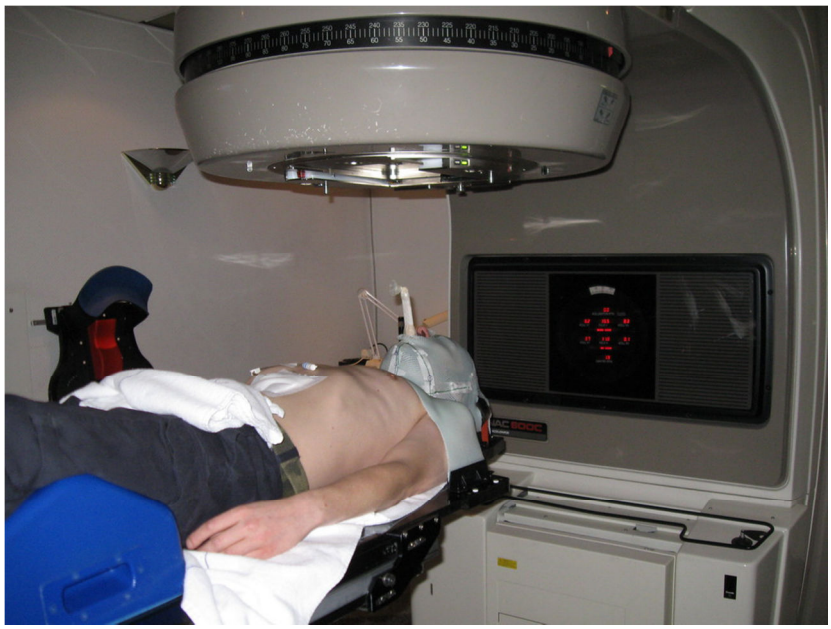
  There are possible side effects of radiation therapy at mouth and throat region depending on the site of radiation, intensity of radiation and period of radiation treatment.

  Commonly seen side effects of Radiation therapy –

- Xerostomia
- Excessive salivation
- Stomatitis / Oral mucositis
- Trismus
- Weight loss
- Hoarseness of voice when radiation given at throat region

- Loss of taste
- Redness, soreness and pain in the radiation treated area
- Damage to salivary glands when radiation given in oral cavity
- Change in colour of skin at the site of radiation therapy
- Damage to jaw bone
- Damage to pituitary and thyroid gland

Fig. 20 : Radiation therapy



3. **Chemotherapy for oral cavity cancer :**

It is a therapy which uses anti-cancer drugs to treat cancer. The route of administration is oral and intra-venous[51].

- **Applications of Chemotherapy (CT)** :

- Chemoradiation – Chemotherapy combined with radiation therapy instead of surgery as main treatment for Cancer.
- Adjuvant Chemotherapy – Chemotherapy mostly given post-surgery to treat any remnant cancer cells.
- Neoadjuvant /induction chemotherapy – Chemotherapy administered to shrink larger cancers pre-surgery to facilitate minimal invasive surgery.
- Chemotherapy to relieve or minimize symptoms of cancers which are two large or have spread in the body.

- **Drugs used in Chemotherapy** :

- Cisplatin
- Carboplatin
- 5 – Fluorouracil (5-FU)
- Paclitaxel
- Docetaxel

Chemotherapy drugs may be used individually or in combinations. Combining the drugs may have better effect to shrink the tumor but also has more side effects.

The medical oncologists advise chemotherapy in cycles. This involves some period of rest after each treatment which allows the body for recovery. Each cycle of chemotherapy may last for few weeks.

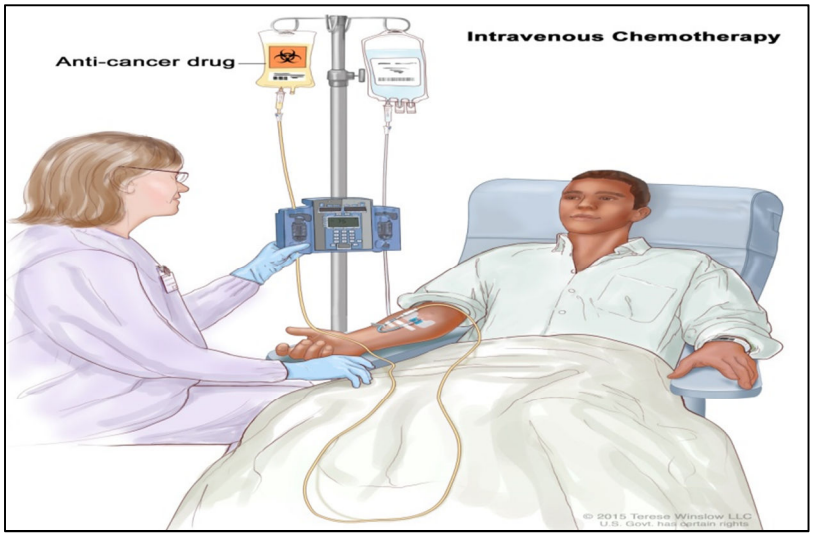
➢ **Possible side effects of Chemotherapy** :

- Stomatitis
- Loss of appetite.
- Hair loss
- Nausea
- Vomiting
- Diarrhea
- Low blood counts
- Decreased WBC count leading to increased chance of infections.
- Reduction in platelets count causing easy bruising or bleeding.
- Reduced RBC count causing fatigue.

The side effects of Chemotherapy depend on the drug selected, the dose of the drug and the duration of treatment.

In severe cases of side effects of chemotherapy with use of drugs like Cisplatin, Loperamide, Paclitaxel and Docetacel, it can cause nerve damage (neuropathy) and related complications.

Fig. 21 : Chemotherapy



j. QUALITY OF LIFE IN ORAL CAVITY CANCER PATIENTS :

WHO defines Quality of Life as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment[52].

Oral cavity cancer is one of the life threatening oral disease in the world. In majority of such cases, it is detected in an advanced stage where the complications are more, therapeutic options are reduced and the prognosis is much worse. This happens mostly due to lack of awareness and delayed screening.

The oral cavity cancer includes various cancers related to different sites of the oral cavity. This mainly has an impact on the oral intake of the patient. The disease itself when starts to manifest in the body hamper the overall health of the patient. The growth inside the oral cavity makes it difficult for the patient to have a proper oral intake, difficulty in swallowing, ulcerations usually accompanied by inflammation inside the oral cavity causes intolerance to hot and spicy food. As the disease progresses, patient has difficulty in opening his mouth so his speech gets hampered and further aggravation may lead to dyspnea which can prove fatal. Sometimes cancer causes deformity in the patient's physical appearance. The limitation or difficulty in oral intake leads to improper nutrition which results in general weakness of the patient. Along with physical debility patient also experiences psychological and social impact causing irritation, anger and ultimately fear in the mind. This ultimately leads to poor quality of life.

As discussed in the previous topics, there are several side effects of surgery, radiation therapy and chemotherapy which hamper the quality of life of the patients who undergo these therapies.

Of the different treatment modalities available for oral cavity cancer management, surgical treatment cause major effects on the quality of life of these patients. It mainly interferes with the esthetic and the functional aspect because the surgical incision and cancer resection often modify the patient's self-perception and his ability to interact with others in

daily social life. These patients cannot hide their post treatment condition. Inspite of the advent in the surgical and reconstruction techniques, effective radio-chemotherapy protocols, it is still a difficult challenge to the best of the Oncologist, Surgeons and Radiologist to maintain a balance in cancer treatment and patient's survival along with preservation of functions, esthetics and quality of life[53].

The cure rate in oral cavity cancer is very low. Side-effects like altered masticatory functions and nutrition, speech disruption, dysphagia, disfigurement is commonly seen. Sometimes conditions like osteo-radionecrosis, fracture insufficiency; bone loss ultimately resulting in bone marrow suppression can also be seen in patients receiving radiation doses in excess of 6000 cGy[54]. Trismus i.e. restricted mouth opening is also a common complaint post oral cancer surgery. This is mainly due to the masticatory muscle damage, contraction and fibrosis. This has severe impact on the oral hygiene, nutrition and speaking ability of the patient. Similarly, xerostomia which is caused due to impairment in the function of salivary glands leads to dryness in the mouth is very oftenly seen in post surgery and radiation treatment. During resection of primary tumors and neck dissection there are several cranial nerves involved which are at high risk[53].

Modern medicine renders some remedies for few of the above mentioned complications which gives some temporary relief but do not cure the condition. In case of xerostomia, patients are mostly advised to keep candies in their mouth, drink plenty of water or use fluoride toothpaste. But these temporarily give relief but don't resolve the xerostomia. In excessive salivation, anti-cholinergic medications like glycopyrrolate are advised which give temporary relief and have limitations for usage. In stomatitis, prophylactic antibacterial or antifungal treatments to clear mouth or oral micro flora are generally advised to the patient. Antimicrobial agents like nystatin, clotrimazole and lozenges are advised which are for temporary relief. Patients having trismus are advised to do jaw exercises and maintain jaw mobility which also helps in a limited manner. In the worst of the cases, where minimal to absence of opening of mouth is seen, to compensate for oral intake, procedures like insertion of nasogastric tube (feeding tube) in the initial stage and jejunostomy tube (J- Tube), percutaneous endoscopic gastrostomy (PEG) tube insertion is done in the later stages. Intake of multivitamins or proteins is advised to compensate for the nutritional deficit which give temporary effect, but don't improve the digestion.

Oral cavity cancer patients face challenges in their day to day life due to hampered functions of the body, sometimes accompanied by deformities. In addition to this, the psychological trauma and fear worsen their state of mind. Thus the Quality of Life of the patients gets affected making the patient's life miserable.

Ayurveda, which is an ancient science and treatment modality primarily aims on maintaining the healthy status in an individual but also has treatments described for various disorders. Healthy status according to Ayurveda includes physical as well as psychological well being. Thus, Ayurveda stands as a helpful medium to treat the various cancers and their complications.

The fundamental concept of Ayurveda includes the Tridosha, Sapta Dhatu, Tri Mala, Srotas, etc. This makes the understanding and diagnosis of the disease or symptom easier with a precise approach and planning to treat the disease.

In the present study, our main focus is to practically implement the principles of Ayurvedic treatment to improve the quality of life of cancer patients. Taking this in consideration we have designed a treatment protocol which will help to pacify the vitiated Doshas which are mainly due to treatment modalities like surgery, radiation and chemotherapy; rejuvenate body functions; restore immunity and improve quality of life.

k. ORAL CAVITY CANCER REHABILITATION –

Rehabilitation is an important part to consider in any therapy. In cancer care and treatment too, a good treatment plan should include appropriate diagnosis initially to a proper rehabilitation post treatment[55].

In oral cavity cancers and their treatments, there may be post treatment functional limitations or side effects. Combined modalities of treatment may have a higher risk for functional deficit post treatment.

Surgical resections may often create large defects which are accompanied by dysfunction and disfigurement. Significant morbidity and tissue related complications are seen after radiation therapy. Functions like salivation, swallowing, mastication, speech may be adversely affected.

There can a wide array of potential deficits which may need one or more professional intervention and thus the patient mostly benefits from multidisciplinary rehabilitation plan. A person's normal way of life may get hampered if the cosmetic or functional impairments are not minimized or corrected.

The main objective of rehabilitation is restoration of appearance and functions in a patient. It mainly depends on the expertise of the medical professionals as well as the physiological and psychological state of the patient.

Rehabilitation in oral cavity cancers requires a clear and systematic planning and may need multidisciplinary interventions viz. oncosurgeons, dental oncologist, prosthetic doctor and related professionals as a part of restoration team. To make it further effective, advice from professionals like nutritionists, dieticians, occupational, physical, speech therapists, psychologists may also be helpful.

B) LITERATURE REVIEW OF CANCER FROM AYURVEDIC PERSPECTIVE

B-I) ANUKTA VYADHI FROM AYURVEDIC PERSPECTIVE :

Cancer, as a disease has not been mentioned directly in Ayurvedic Samhita. With the help of 'Atidesha' and 'Uhyam' Tantrayukti we can try to understand cancer from Ayurvedic perspective[56,57].

अतिदेशो नाम यत् किंचित् एव प्रकाश्यार्थमनुक्तार्थसाधनायैव एवमन्यदपि प्रत्येतव्यमिति परिभाष्यते ।

च.सि. १२/४२ (श्री चक्रपाणि टीका)

ऊह्यम नाम यदनिबध्दं ग्रन्थे प्रशया तर्क्यत्वेनोपदिश्यते।

च.सि. १२/४३ (श्री चक्रपाणि टीका)

Atidesha Tantrayukti means Sutra or principle explained in specific context and at the same time applicable to another context. Uhyam Tantrayukti basically means logical interpretation about a scientific knowledge as stated in our ancient classical texts for better understanding.

In our Ayurvedic texts, there are guidelines or Sutras regarding specific diseases, their etio-pathogenesis, signs and symptoms and most importantly the management or treatment. A Vaidya can logically apply these principles and correlate them to Anukta Vyadhi like cancer, etc. which are not mentioned in the classics.

Many diseases which are described in Ayurvedic text show similarity with cancer. The etiology (Nidan) pathogenesis (Samprapti), treatment (Chikitsa) of cancer can be described by considering the basic principles of Ayurved**.**

सर्व एव निजा विकारा नान्यत्र वातपित्तकफेभ्यो निर्वर्तन्ते;

यथा हि - शकुनि सर्व दिवसमपि परिपतन् स्वां छायां नातिवर्तते,

तथा स्वधातुवैषम्यनिमित्ताः सर्वे विकारा वातपित्तकफान्नतिवर्तन्ते;

वातपित्तश्लेष्मणां पुनः स्थानसंस्थानप्रकृतिविशेषनभिसमीक्ष्य

तदात्मकानपि च सर्वविकारांस्तानेवोपदिशन्ति बुध्दिमन्त ।

च. सू. १९ /५

Tridosha i.e. Vata, Pitta and Kapha are the main cause for manifestation of any type of disease in the body. Charakacharya has given an example of a bird by stating that a bird flies every day, but does not leave its shadow; similarly Doshas are always pivotal in causation of diseases[58].

विकारनामाकुशलो न जिह्मीयात् कदाचन।

न हि सर्वविकाराणां नामतोस्ति ध्रुवा स्थितिः।।४४।।

स एव कुपितो दोषः समुत्थानविशेषतः।

स्थानान्तरगतश्चैव जनयत्यामयान् बहून्।।४५।।

तस्माद्विकारप्रकृतीरधिष्ठानान्तराणि च।

समुत्थानविशेषांश्च बुद्ध्वा कर्म समाचरेत् ।।४६।।

यो ह्येतत्त्रितयं ज्ञात्वा कर्माण्यारभते भिषक् ।

ज्ञानपूर्वं यथान्यायं स कर्मसु न मुह्यति।।४७।।

च. सू. - १८/४४-४७

There are innumerable diseases divided on the basis of pain, color, etiology, symptoms, location, name, etc. Charakacharya has clearly mentioned that a physician should not bother too much to understand name of the disease. The reason is that same vitiated Dosha causes various disorders according to variation in etiology and location. Hence one should have complete knowledge about the Vikaraprakruti - state of vitiated, Dosha, Dhatu, Mala causing disease, Adhisthanantarani - site of vitiated Dosha and Samutthanavishesha -

cause of vitiation of Dosha . After thorough knowledge of these three important aspects, one does not get into dilemma about the appropriate treatment to be undertaken and finally achieves success in his undertaking[59,60].

त एव अपरिसंख्येया भिद्यमाना भवन्ति हि ।

रूजावर्णसमुत्थानस्थानसंस्थाननामभिः ।।

व्यवस्थाकरणं तेषां यथास्थूलेषु संग्रहः ।

तथा प्रकृतिसामान्यं विकारेषु उपदिश्यते ।।

च. सू. १८ । ४२ - ४३

B-II) DIAGNOSIS OF CANCER FROM AYURVEDIC PERSPECTIVE :

Cancer is not mentioned in Ayurvedic Samhitas as a single disease. Various diseases mentioned in Ayurvedic texts like Dushta Vrana, Dushta Granthi, Dushta Arbuda, Dushta Vranashotha, Dushta Nadivrana, Dushta Visarpa show similarity with cancer. Malignant tumours are divided as solid tumors and non-solid tumors in modern literature.

Non-solid tumors which mainly include Leukemia, Hodgkin's diseases and Non-Hodgkin's disease resemble :

1. Rasa - Rakta Dhatugata Jwara- (Fever pertaining to Rasa Dhatu & Rakta Dhatu)
2. Raktapitta - (Bleeding disorders)
3. Pandu - (Anemia)
4. Raktaja Krumi - (Worms's causing skin disorders)

Solid malignant tumors are similar to diseases like -

1. Dushta Shotha - (Malignant oedema)
2. Dushta Vrana - (Malignant wounds / ulcers)
3. Dushta Granthi - (Malignant nodes)
4. Dushta Arbuda - (Malignant tumours)
5. Dushta Visarpa - (Malignant spreading cellulitis)
6. Dushta Nadivrana - (Malignant fistula / sinus)
7. Dushta Mansapradoshaja Vikara - (Malignant diseases caused due to vitiation of Mansa Dhatu)

B-III) STAGES OF CANCER FROM AYURVEDIC PERSPECTIVE :

Basically Granthi, Arbuda, Vidradhi, Visarpa, Nadivrana and Mansapradoshaja Vikara are various forms of Shotha (oedema), because Utsedha (growth / swelling) is the common and predominant symptom in them[61,62,63,64,65,66].

व्रण, व्रणशोथ, ग्रंथी, अर्बुद, विसर्पादि एकदेशीय शोथ

(च. सू. १८ । त्रिशोथीय अध्याय)

दुष्ट ग्रंथी

वातादयो मांसं असृक् च दुष्टाः
संदूष्य मेदः च कफनुविद्धम्।
वृत्तोन्नतं विग्रथितं तु शोफं
कुर्वन्त्यतो ग्रंथिरिति प्रदिष्टः ।।

(सु. नि. ११ / ३)

सामान्य लक्षणे :

- वृत्त शोथ
- उन्नत शोथ
- कठीण शोथ

दुष्ट अर्बुद

गात्रप्रदेशे क्वचित् एव दोषाः
संमूर्च्छिता मांसं अभिप्रदूष्य ।
वृत्तं स्थिरं मन्दरूजं महान्तम्
अनल्पमूलं चिरवृद्धी अपाकम् ।।
कुर्वन्ति मांसोपचयं तु शोफं
तद् अर्बुदं शास्त्रविदो वदन्ति ।

(सु. नि. ११ / १३ - १४)

दुष्ट विद्रधि

त्वक् रक्त मांस मेदांसि प्रदूष्य अस्थिसमाश्रिताः ।

दोषाः शोफं शनैः घोरं जनयन्ति उच्छ्रिता भृशम् ।।

(सु. नि. ९ / ४)

दुष्टरक्तातिमात्रत्वात् स वै शीघ्रं विदह्यते ।

(च. सू. १७ / ९५)

अंतः शरीरे मांसासृक् आविशन्ति यदा मलाः ।

तदा सञ्जायते ग्रंथिः गंभीरस्थः सुदारूणः ।।

(च. सू. १७ / ९३)

दुष्ट विसर्प

त्वक् मांस शोणितगताः कुपिताः तु दोषाः ।

सर्वाङ्गसारिणं इह अस्थितं आत्मलिङ्म् ।।

कुर्वन्ति विस्तृतं उन्नतं आशु शोफम् ।

तं सर्वतः विचरणात् च विसर्पं आहुः ।।

(सु. नि. १० / ३)

नाडीव्रण

शोफं न पक्वं इति पक्वं उपेक्षते यो

यो वा व्रणं प्रचुरपूयं असाधुवृत्तः ।।

अभ्यन्तरं प्रविशति प्रविदार्य तस्य

स्थानानि पूर्वविहितानि ततः स पूयः ।

तस्य अतिमात्रगमनात् गतिः इति अतः च

नाडी इव यद् वहति तेन मता तु नाडी ।।

(सु. नि. १० / ९ -१०)

Ayurvedic treatment differs in various Awastha (stages) of the disease.

Stages of cancer can be correlated with stages of Shotha as described in following manner in Ayurvedic Samhitas :

a) According to progression of Shotha[67]:

1. Aama Awastha
2. Pachyamana Awastha
3. Pakwa Awastha (i.e. acutely tender stage) of Shotha (oedema)

आमं विपच्यमानं च सम्यक् पाकघ्न यो भिषक् ।

जानीयात् स भवेद्वैद्यः शेषास्तस्करवृत्तयः ।।

सु. सू. १७/११

The Aama (unripped stage), Pachyamana (semi -ripped stage) and Pakwa Awastha (stage of inflammation), which are described in Shotha (swelling), are also observed in above mentioned diseases.

b) According to Gati and Swarupa of Dushta Dhatu causing disease:

1. Dhatugata Awastha[68]
2. Dhatupaka Awastha[69]

मांसदोषेण जानीयात् अर्बुदं मांससंभवम् ।

शीर्यन्ते यस्य मांसानि यत्र सर्वाः च वेदना ।।

विद्यात् तं मांसपाकं तु सर्वदोषकृतं भिषक् ।

सु. नि. १४ । १४

In Gata Vata, Vata being located at a particular site gets vitiated and later causes specific symptoms pertaining to that particular Sthana. The concept states invasion and manifestation of particular disease in successive Dhatus (deeper and deeper tissues) namely Rasa, Rakta, Mansa, Meda, Asthi, Majja and Shukra, as disease progresses. Sushrutacharya has also explained Mansa Paka leading to formation of Arbuda.

c) According to Sadhya - Asadhya Awastha of the disease (curable & non-curable stage):

1. Sadhya Vyadhi
2. Asadhya Vyadhi

सुखसाध्यं मतं साध्यं कृच्छ्रसाध्यमथापि च ।
व्दिविधं चाप्यसाध्यं स्याद् याप्यं यच्चानुपक्रमम् ।।
साध्यानां त्रिविधश्चाल्पमध्यमोत्कृष्टतां प्रति ।
विकल्पो न त्वसाध्यानां नियतानां विकल्पना ।।

च. सू. १०/७

In Sushrut Samhita and Charak Samhita Sutrasthan, Adhyaya tenth, Mahachatushapada, criteria of Sadhya – Asadhya Vyadhis are mentioned[70]. As in many patients, cancer is diagnosed in late stage i.e. in Dhatupaka Awastha (stage of loss of tissues) and Dhatugata Awastha; these are the signs of Asadhyatwa (non-curable stage). At this stage also, physician should try his best to control further growth and to give relief to the patients.

Shotha :

ग्रंथादिभ्यो विलक्षणः पृथुर्ग्रथितः समो विषमोवात्वड्मांसस्थायी
दोषसंघातः शरीरैकदेशोत्थितः शोफ इत्युच्यते ।

सु.सू. १७-३

Sushrutacharya defines 'Shotha' as any vitiation of the Doshas causing an accumulation which may have a definite or irregular form occurring at skin or flesh[71]. It can occur locally (Ekanga) in the body or generally (Sarvanga).

रोगाश्चोत्सेधसामान्यदधिमांसार्बुदादयः ।

विशिष्टा नामरुपाभ्यां निर्देश्याः शोथसङ्ग्रहे ।।

च. सू. १८/३३

Charkacharya describes in detail about Shotha in his 'Trishothiya Adhyaya'. He mentions that Utsedha is a common symptom seen in any Shotha. Shotha is seen in various forms and parts of the body viz. Adhimansa, Arbuda, etc[72]. These all are a specific symptoms and classifications of 'Shotha'.

Such common and specific symptoms are also seen in the oral cavity or 'Mukha'. In normal individual, the Tridoshas are in harmony and constitute the different parts of the body in different proportions. Due to various etiological factors, the Doshas get vitiated and affect the Dhatus. In 'Mukha Pradesh' (oral cavity) too, various diseases and symptoms are seen due to vitiated Doshas.

B-IV) MUKHAGATA ROGA:

Shalakya Tantra is one of the eight branches of Ayurveda which particularly deals with the diseases occurring in head, neck, eyes, ear and oral cavity. Mukhagata Roga is described in ancient Ayurvedic texts like Sushrut Samhita, Charak Samhita, Astanga Sangraha, Yoga Ratnakar, Madhav Nidan, etc.

Mukha– Mukha (Oral cavity) consists of 7 different parts[73,74] –

ओष्ठौ च दंतमूलानि दन्ता जिव्हा च तालु च ।

गलो गलादि सकलं सप्तांगं मुखमुच्यते ।।

यो.र.भा. २ पा.४८२

तत्रायतनानि-ओष्ठौ, दन्तमूलानि, दंताः जिव्हा, तालु कंठः, सर्वाणि चेति ।

सु.नि. १६-३

1. Oshtha (Lips)
2. Dantmoola (Gums)
3. Danta (Teeth)
4. Jivha (Tongue)
5. Talu (Palate)
6. Gala (Throat)
7. Galadi (All of the above mentioned parts as a whole).

Aetiological factors (Nidan) of Mukhagata Roga :

Following etiological factors are taken into consideration while describing Mukhagata Roga in ancient literature -

मत्स्यमहिषवाराहपिशितामलकमूलकम ।
माषसूपदधिक्षीरसुक्तेक्षुरसफाणितम् ।
अवाक्शय्या च भजतो व्दिषतो दंतधावनम् ।
धूतच्छर्दनगंडूषानुचितं च सिराव्यधम् ।

वा.उ.२१-१, २

Dietary factors like fish, buffalo meat, pork which are heavy to digest; raddish, soup of black gram, curds, milk and milk products, vinegar, sugarcane juice and jaggery syrup consumed in excessive proportion can cause diseases of oral cavity. Also, consumption of excessive hot and spicy food items can lead to diseases of oral cavity[75].

Sleeping in prone position (Avakchhaya), improper brushing habits, not following procedures like Dhoomapana (inhalaling medicated fumes), Vamana (emesis), Gandusha (gargling with medicated decoctions) and Raktamokshana (blood-letting) whenever required can also lead to diseases of oral cavity.

Pathogenesis (Samprapti) :

Pathogenesis of oral diseases is described as follows -

क्रुध्दाः श्लेष्मोल्बणा दोषाः कुर्वंत्यंतर्मुखे गदान् ।

वा.उ.२१-३

Improper dietary habit and improper behavioral habit leads to vitiation of Tridosha with the dominance of Kapha Dosha to develop oral cavity diseases[76].

Types of Mukha Roga :

मुखरोगाः पंचषष्टिर्भवन्ति सप्तस्वायतनेषु ।

तत्राष्टावोष्ठयोः, पंचदश दंतमूलेषु, अष्टौ दंतेषु, पंच जिव्हायां,

नव तालुनि सप्तदश कंठे, त्रयः सर्वेष्वायतनेषु ।

सु.नि. १६-३

There are various differences of opinion regarding the Samkya Samprapti or number of types of Mukha Roga[77].

Table 10 : Types of Mukhgata Roga

Site	Sushrut Samhita	Astanga Hridaya	Charak Samhita	Yoga Ratnakar	Madhav Nidan
Oshtha	08	11	-	08	08
Dantmoola	15	13	-	16	15
Dant	08	10	-	08	08
Jivha	05	06	-	05	05
Talu	09	08	-	09	09
Kanta	17	18	-	18	17
Sarvamukha	03	08	-	03	03
Ganda	-	01	-	-	-
Total	**65**	**75**	**64**	**67**	**65**

Symptoms of Mukhagata Rog (Samanya Lakshanas) :

The general symptoms of Mukha Roga have been mentioned in the Vedana Adhaya of Kashyapa Samhita in context with pediatric group[78]. These are as follows –

लालास्त्रवणमत्यर्थं स्तनव्देषारतिव्यथाः ।
पीतमुद्गिरति क्षीरं नासाश्वासी मुखामये ।।

का.सं.सू. २५-८

These symptoms can be correlated to other age group also. These symptoms can be in the form of -

1. Excessive salivation
2. Anorexia
3. Regurgitation
4. Tachypnoea
5. Loss of appetite
6. Generalized weakness.

Correlation of Mukha Roga with oral cavity cancer and its symptoms:

In this context, few of the diseases of Mukha Roga which are relevant for the present study can be correlated with malignant manifestations. These are as follows –

Table 11 : Correlation of Mukha Roga with oral cavity cancer and its symptoms

Sr. No.	Name of the Mukha Roga	Site	Correlation with	Vitiated Dosha	Signs and Symptoms	Treatment
1	**Kaphaj Jivha Kantaka**[79,80]	Jivha (Tongue)	Chronic glossitis, Leucoplakia	Kapha	Jivha becomes heavy, thick, wide and is scattered with thorny buds resembling Shalmali Kantaka and is associated with pain, discomfort, itching sensation.	Lekhana or Gharshana with the leaves of Gojihva or Shephalika to remove the impure blood. Rakta Mokshana. Pratisarana – Local application over tongue lesions with Trikatu, Sarshapa + Saindhav + Madhu. Kavala and Gandusha–Shweta Sarshapa + Saindhav.
2	**Galarbuda**[81]	Gala (Throat)	Tumor in throat region in the vicinity of tongue	Tridosha	Hard, immobile, painless, non-supportive, reddish tumour in the throat in the vicinity of tongue.	Chedana (Excision) to be done if the growth is small. Pratisarana – Local application over the lesion with Sarja Kshara + Shunthi + Madhu. Gandusha– Gargling with Guduchi + Nimba Kashaya + Honey + Tila Taila. Nasya and Abhyanga.

3	**Kapharbuda**[82,83]	Kapola (Buccal Mucosa)	Cancer of Buccal Mucosa	Tridosha, Kapha dominance	Blackish-white color tumor in the oral cavity specifically in the internal surface of Kapola i.e. cheeks.	Chedana to be done if the growth is small. Pratisarana – Local application over the lesion with Sarja Kshara + Shunthi +Madhu.
4	**Sarvasara Mukha Roga**[84]	Oral cavity	Pre-malignant and malignant stage.	Tridosha Pitta dominance	Inflammation or ulceration in the oral cavity mainly seen in all types of oral cavity cancers.	Mukha Dhawana – Triphala + Patha + Mudwika + Jati Pushpa. Gandusha and Nasya – Siddha Vatahara Tail. Snehika Dhoomapana.
5	**Puti Mukhta**[85,86]	Oral cavity	Halotosis or oral unhygienic condition	Tridosha + Rakta	Foul smell comes from the mouth.	Tikshna Nasya. Mukha Dhawana – Lodhra + Padmaka. Dhoomapana.
6	**Gala graha**[87]	Kantha (Oropharynx region)	Tumour in throat region	Tridosha, Kapha dominance	Immobile swelling inside the throat region associated with fever, anorexia and excessive salivation.	Gandusha.

7	**Talu Arbuda**[88, 89]	Talu (Palate)	Carcinoma of Palate	Tridosha + Rakta	Red colored tumour resembling Padma Karnika.	Asadhya
8	**Talu Shosha**[90,91]	Talu (Palate)	Atrophy of Palate	Tridosha with Vata and Pitta dominance	Dryness in mouth, Dyspnoea.	Vata Pitta-nashak. Gandusha – Amla Dravya. Nasya – Ghruta. Snigdha Dhoomapana.
9	**Talu Paka**[92,93]	Talu (Palate)	Ulceration of Palate	Tridosha with Pitta dominance	Formation of ulcer in the palate.	Gandusha – Sheeta, Kashaya, Madhur. Pratisarana.
10	**Alasa**[94,95]	Jivha (Tongue)	Sublingual abscess or carcinoma	Tridosha with Kapha and Rakta dominance	Progressive swelling underneath tongue causing immobilization and suppuration.	Asadhya, In early stage – Virechana, Gandusha, Dhoomapana, Vamana, etc

11	**Danta Vidradhi**[96,97]	Dant Moola (Alveolus)	Alveolar abscess	Tridosha with Rakta dominance	Swelling of gums associated with pain and edema, after suppuration discharges blood stained pus.	Gandusha – Triphala, Nimba Nasya – Yashtimadhu Ghruta
12.	**Rakta Arbuda**[98]	Oshtha (Lip)	Swelling at lip	Tridosha with Rakta	Formation of reddish colored swelling which resembles Kharjura fruit.	Asadhya
13	**Hanu graha**[99,100]	Hanu (Jaw)	Trismus	Tridosha with Vata dominance	In this condition there is difficulty in opening of mouth and disability in movement of jaw.	Snigdha Chikitsa

These Mukharoga are seen as disease itself or can be in form of symptoms of side-effects of surgery, radiation and chemotherapy as well as symptoms. In such patients, along with the cardinal signs and symptoms related to oral cavity, symptoms of Rasavaha Srotas Dushti like loss of taste sensation (Aruchi), nausea (Hrullas), etc. are also seen[101].

अश्रध्दा चारुचिश्चास्यवैरस्यमरसज्ञता ।

ह्रल्लासो गौरवं तन्द्रा सङ्गमर्दो ज्वरस्तमः ।।

च. सू. २८/९

Along with the above mentioned diseases, we should also consider the diseases mentioned in Mansapradoshaja Vyadhi[102].

शृणु मांसप्रकोपजान् ।

अधिमांसार्बुदंकीलंगलाशालूकशुण्डिका ।।

पूतिमांसालजीगण्डगण्डमालोपजिव्हिकाः ।

विद्यान्मांसाश्रयात् ।।

च. सू. २८/१३-१४

मांसजानान्तुसंशुध्दिः शस्त्रक्षाराग्निकर्म च ।

च. सू. २८/२६

Dushta Arbuda is mentioned as one of Mansapradoshja Vyadhi in Charak Samhita. The line of treatment in this condition is Shastrakrma, Agnikarma and Kshara Karma[103].

Agni Karma, Kshara Karma and Shastra Karma in treatment of cancer :

विपाट्य चोद्धृत्य भिषक् सकोशंशस्त्रेण दग्ध्वा व्रणवच्चिकित्सेत् ।
अदग्ध ईषत् परिशेषितश्च प्रयाति भूयोऽपि शनैर्विवृध्दिम् ।।
तस्मादशेषः कुशलैः समन्ताच्छेद्यो भवेव्दीक्ष्य शरीरदेशान् ।

च.चि. १२-८२, ८३

क्षाराग्निशस्त्राण्यसकृव्दिदध्यात् प्राणानहिंसन् भिषगप्रमत्तः ।

सु.चि. १६/३८

Kshara Karma, Agni Karma & Shastra Karma are the choice of treatment in Arbuda and Granthi. These treatment need to be carried out without injuring / causing harm to the vital organ involved[104, 105].

According to Ayurveda generally complete excision of Granthi / Arbuda (tumor) is recommended. After excising the tumor growth, Agnikarma (type of cauterization) is to be carried out. This is helpful in complete removal of tumor. Growth if is not removed completely, recurrence may take place.

Therefore it is advisable to remove the tumor in accordance to the organ involved. As per the modern terminology, surgery can be correlated to Shastra Karma, chemotherapy to Kshara Karma & radiation therapy to Agni Karma.

Rationale for Selection of Basti, Nasya, Mukhopakrama, Shirodhara and Karnapurana for treating oral cavity cancer patients :

Vitiation of Doshas is the main cause for disease manifestation.

वातादृते नास्ति रुजा न पाकः

पित्तादृते नास्ति कफाच्च पूयः ।

तस्मात् समस्तान् परिपाक काले

पचंति शोफास्त्रय एव दोषाः ।।

सु.सू. १७/७

ततः शोफरुजास्त्राव दाहपाकानवाप्युयात् ।

सु.सू. १९

टीका - शोफरुजे वातस्य, आस्त्रावः कफस्य, दाहपाकौ पित्तस्येति ।

Vitiation of Trisdoshas causes 'Shotha' or Vranashotha'. In this, 'Ruja' is due to Vata dominance, 'Paka' due to Pitta dominance and 'Srava' due to Kapha dominance[106]. Ayurveda has also described concepts like 'Dhatugata Awastha' and 'Dhatupaka Awastha' which help us to understand the extent of Dosha vitiation and the factors involved enabling us to decide a specific and better treatment plan.

पित्तंपंगुकफः पंगुपंगवोमलधातवः ।

वायुना यत्र नीयन्ते तत्रगच्छन्तिमेघवत् ।।२५।।

शा.सं.पू.खं. ५/२५

Vata Dosha is considered to be the most powerful amongst all the Tridoshas due to its 'Chala' characteristic (Guna). It has the capability of motion and also to move others[107].

Sushrutacharya has described 'Shashthi Upakrama' as the treatment for Vranashotha. It includes sixty different procedures which are useful to treat the Vranashotha[108].

तस्य व्रणस्य षष्टिरुपक्रमाभवंति । तद्यथा-अपतर्पणमालेपः
परिषेकोऽभ्यंगः स्वेदोविम्लापनमुपनाहः पाचनंविस्त्रावणंस्नेहोवमनं
विरेचनंछेदनंभेदनंदारणंलेखनमेषणमाहरणं व्यधनं विस्त्रावणंसीवनं
संधानंपीडनंशोणितास्थापनंनिर्वापणमुत्कारिकाकषायो वर्तिः कल्कः
सर्पिस्तैलं रसक्रियाऽवचूर्णनं व्रणधूपनमुत्सादनमवसादनंमृदुकर्म
दारुणकर्म क्षारकर्मपांडुकर्मप्रतिसारणंरोमसंजननंलोमापहरणं
बस्तिकर्मोत्तरबस्तिकर्मबंधः पत्रदानंकृमिघ्नंबृंहणंविषघ्नंशिरोविरेचनं
नस्यंकवलधारणंधूमोमधु सर्पियंत्रमाहारो रक्षाविधानमिति ।

सु.चि. १ -८

Most of the diseases which come under Mukha Roga show some or other type of Shotha or Vrana in its pathogenesis and also while studying the treatment of these diseases, procedures like Dhoopana, Pratisarana, Kavala- Gandusha, Lepa, Sweda, etc. have been described extensively along with Shodhana and Shastra Karma.

In our present study, while designing Panchakarma protocol in oral cavity patients we have mainly considered vitiation of Vata and Pitta and also to some extent Kapha and hence designed the treatment protocol applying few procedures from 'Shasthi Upakarma.' Patients who have cancers of oral cavity have vitiated Tridoshas and such patients after undergoing conventional treatment also experience further vitiation of Tridoshas which sometimes make the side effects fatal than the disease. Also while battling the dreaded disease cancer, the morale or psychology of the patient is affected. Therefore of the sixty allied procedures and also referring to the treatment mentioned for various Mukha Roga, following procedures are selected for the present protocol.

1. Snehana
2. Swedana
3. Basti – Matra Basti
4. Nasya

5. Gandusha
6. Mukha Pratisarana
7. Shirodhara
8. Karnapurana

Snehana :

Snehana procedure in the present study refers to Bahya Snehana which is also called as Abhyanga.

स्नेहाभ्यंगाद् यथा कुम्भश्चर्मस्नेहविमर्दनात् ।
भवत्युपांगदक्षश्च दृढः क्लेशसहो यथा ।। ८५।।
तथा शरीरमभ्यंगाद् दृढं सुत्वक् च जायते ।
प्रशान्तमारुताबाधं क्लेशव्यायामसंसहम् ।। ८६।।

च.सू. ५/८५-८६

Snehana is described as the oleation which is a type of lubrication given to the body and helps to get rid of the various disorders of vitiated Vata Dosha and to increase the endurance for performing various physical activities. Regular use of Snehana helps to promote the strength and lustre of the human body. Charakacharya has described importance of Snehana by giving illustrations of application of oil in a clay pot, to a leather object and to the axis of a wheel for proper functioning[109].

स्पर्शनेभ्यधिको वायुः स्पर्शनं च त्वगाश्रितम् ।
त्वच्यश्च परमभ्यंगस्तस्मात्तं शीलयेन्नरः ।।८७।।

च.सू. ५/८७

The presence of Vayu predominantly at the Twacha (skin) enables the sense of touch at skin. Abhyanga has been described as the best promoter for lustrous and healthy skin.

People who practice Abhyanga on a regular basis are prone to have lesser disorders due to any trauma and can tolerate physical exertions. Snehana helps to endow lustrous and smooth skin, strong physique and longevity.

न चाभिघाताभिहतं गात्रमभ्यंगसेविनः ।

विकारं भजतेत्यर्थबलकर्मणिवाक्वचित् ।। ८८ ।।

सुस्पर्शोपचितांगश्चबलवान् प्रियदर्शनः ।

भवत्यभ्यंगनित्यत्वान्नरोल्पजर एव च ।।८९।।

च.सू. ५/८८-८९

अभ्यंगस्तु दोषमालोक्योपयुक्तो दोषोपशमंमृदुतां च करोति ।

सु.चि. १/१९

Swedana :

स्नेहपूर्वं प्रयुक्तेन स्वेदेनावजितेनिले ।

शुष्काण्यपि हिकाष्ठानिस्नेहस्वेदोपपादनैः ।

नमयन्ति यथान्यायं किंपुनर्जीवतोनरान् ।।५।।

च.सू. १४/४-५

स्नेहक्लिन्ना (कोष्ठगा) धातुसंस्थाश्चदौषाः ।

स्वस्थानस्था येच मार्गेषुलीनांः ।

सम्यक् स्वेदैर्योजितैस्ते द्रवत्वम् ।

प्राप्ताकोष्ठं शोधनैर्यात्यशेषम् ।।

अग्नेर्दीप्तिमार्दवंत्वकंप्रसादं ।

भक्तश्रध्दांस्त्रोतसांनिर्मलत्वं ।।

कुर्यात्स्वेदो हंतिनिद्रांसतंद्रा ।

संधीन्स्तब्धांश्चेष्टायेदाशु युक्तः ।।

सु.चि. ३२/२१, २२

Swedana practiced after Snehana helps to pacify the vitiated Vata Dosha[110].

Bahya Snehana i.e Abhyanga is mainly responsible to cause Mriduta of Doshas and Swedana causes Vilayana i.e liquefication of the accumulated Doshas resulting in their traversing to the Koshtha (abdomen) from where they can be eliminated by appropriate Shodhana method. The benefits of Swedana are to promote the Agni, healthy, soft and lustrous skin, purifies the Srotas, increases appetite, and reduces lethargy, drowsiness and excess of sleep. Also, it reduces muscle stiffness and facilitates movements of joints in the body[111].

Charakacharya describes the importance of Snehana and Swedana by giving example of a dry stick, which breaks if tried to be bend but if Sneha (oil) and Swedana is applied to the same stick, it bends instead of breaking.

Matra Basti :

Basti Chikitsa is the most important treatment modality among the Panchakarma. Basti is not only best for Vata disorders but also equally effective in Pitta, Kapha, Rakta, Sansarga and Sannipatika disorders.

बस्तिर्वार्तेच पित्तेचकफेरक्तेच शस्यते ।

संसर्गेसंन्निपाते च बस्तिरेवहितः सदा ।।

सु.चि. ३५-३

शाखागताः कोष्ठगताश्चरोगाः मर्मोर्ध्वसर्वावयवांगजाश्च ।

ये संतितेषांनहि काश्चिदन्यो वायोः परंजन्मनिहेतुरस्ति ।।

विण्मूत्रपित्तादि मलाशयानां विक्षेपसंघातकरः स यमास्त् ।

तस्यातिवृध्दस्य शमाय नान्यद् वस्तिंविनाभेषजमस्तिकिंचित् ।

तस्याचिकित्सार्धमिति ब्रुवन्तिसर्वाचिकित्सामपिवस्तिमेके ।।

च.सि. १/३८-४०

Vata is mainly responsible for manifestation of diseases related to Shakha, Koshtha, Marma and other sites in the body as it is the main governing factor for their functioning. It also

controls the expulsion and retention of the faeces, urine, Pitta from their respective sites and hence Basti is the remedy of choice for pacification of aggravated conditions. It is also described as 'Ardha Chikitsa'[112].

पक्वाशये तथा श्रोण्यां नाभ्यधस्ताच्च सर्वतः ।।
सम्यक्प्रणिहितोबस्तिः स्थानेष्त्रेतेषुतिष्ठति ।। २४ ।।
पक्वाशयाव्दस्तिवीर्यखैर्देहमनुसर्पति ।।
वृक्षमूलेनिषिक्तानामपां वीर्यमिव द्रुमम् ।।२५।।

सु.चि.३५/२४-२५

Sushrutacharya has describes the mode of action of Basti by giving an example of the roots of a tree which receive nourishment from the soil and distributes it to all the other parts of the tree, similarly Basti when properly administered reaches Pakvashaya, Shroni and all the regions below Nabhi. Basti with its Veerya get absorbed in Pakwashaya and then circulates all over the body, reaches the site of disease manifestation and pacifies the vitiated Doshas[113].

Matra Basti is a type of Sneha Basti. The dosage of Matra Basti is low, it is about half of Anuvasana Basti i.e. six tola and so there is no fear of any complications. It is considered safe and very convenient in today's life.

कर्मव्यायामभाराध्वया(पा)नस्त्रीकर्षितेषु च ।
दुर्बले वातभग्ने च मात्राबस्तिः सदा मतः ।।५२।।
यथेष्टाहारचेष्टस्य सर्वकालं निरत्ययः ।
ह्रस्वायाः स्नेहमात्राया मात्राबस्तिः सभो भवेत् ।।५३।।
बल्यंसुखोपचयं च सुखं सृष्टपुरीषकृत् ।
स्नेहमात्राविधानं हि बृंहणं वातरोगनुत् ।।५४।।

च.सि. ४/५२-५४

According to Charakacharya, Matra Basti is always applicable to those emaciated due to overwork, physical exercise, weight lifting, long travels on vehicles and indulgence in women in debilitated person as well as in those afflicted with Vata disorders[114].

Matra Basti is promotive of strength without any demand of strict regimen of diet and causes easy elimination of Mala and Mutra. It performs the function of Bruhana and helps to pacify Vata dosha.

Shirodhara :

Ayurveda has also emphasized on the 'Manovaha Srotas' as well as 'Satvavajay Chikitsa' in the diagnosis and treatment aspect which makes it unique from others. In Ayurvedic texts, four types of Murdha Tail (Oil application on the head) have been described.

They are –

a. Abhyanga
b. Seka
c. Pichu
d. Basti

अभ्यंगसेकपिचवो बस्तिश्चेति चतुर्विधम् ।।२३।।

मूर्धतैलंबहुगुणंतव्दिद्यादुत्तरोत्तरम् ।

अ.ह्र.सू. २२/२३

जयति जनयतीन्द्रियप्रसादं स्वरहनुमूर्धबलं च मूर्धतैलम् ।।३४।।

अ.ह्र.सू. २२/३४

Shirodhara can be included in 'Seka' and helps in pacification of the 'Shirogata Vata' and promotes proper functioning of sense organs, strengthen the joints of head and neck region[115].

Gandusha :

Gandusha is one of the Mukhopkrama. Mukha i.e. the oral cavity is the most important part of the digestive system. According to Ayurveda, it is the site with predominance of Kapha Dosha and cause of many oral diseases if not properly maintained. Hence oral hygiene is very important. Gandusha is a procedure where medicated liquid is held still in the mouth for a certain period of time[116]. The main aim is to keep the mouth clean.

सुखं संचार्यते या तुमात्रा या कवलेस्मृता ।

असंचार्यातु या मात्रागंडुषः परिकीर्तितः ।।

सु.चि.४०/६२

कफपूर्णास्यता यावत्स्त्रवद्घ्राणाक्षताथवा ।

असंचार्योमुखेपूर्णेगण्डूषः कवलोन्यथा ।। ११ ।।

अ.हृ.सू. २२/११

तत्रद्रवेणगंडूष कल्केनकवलः स्मृतः ।।

शा.सं.उ.खं. १०/४

मन्याशिरःकर्णमुखाक्षिरोगाः प्रसेककण्ठामयवक्त्रशोषाः।

हृल्लासतन्द्रारुचिपीनसाश्च साध्या विशेषात्कवलग्रहेण ।।१२।।

अ.हृ.सू. २२/१२

Gandusha is very useful to alleviate the disorders of head, neck and throat. It also helps in conditions like excessive salivation, dryness of mouth, nausea, lethargy, anorexia and rhinitis[117].

दुर्गंधाना क्लेदवतां पिच्छिलानां विशेषतः ।

कषायैः शोधनं कार्यं शोधनैः प्रागुदीरितैः ।।

सु.चि. १/५३, ५४

गण्डूषः कफव्रणहरद्रव्येण।

सु.चि. २२/४८

त्रिफला खदिरो दार्वी न्यग्नोधादिर्बला कुशः ।

निंबकोलकपत्राणि कषायाः शोधना मतः ।।

च.चि. २५/८४

Gandusha, with special reference to Vrana Chikitsa, helps in reducing the foul smell, exudate, stingy and stickiness in the mouth[118]. Shodhana Kashaya (Decoction mainly of astringent taste) is useful in the cleaning and purification of Vrana. Medicinal herbs like Triphala, Khadira, Daruharidra, Nimba, etc. have been described to be effective in such conditions. Mukha Shodhana and Vrana Ropana' is also an important action of Gandusha Kalpana which helps to cleanse the debris and unwanted plaque in the oral cavity and promotes oral hygiene.

Mukha Pratisarana :

Mukha Pratisarana is a procedure in which medicated preparation is applied inside the oral cavity. There are three types of Pratisarana viz. Kalka, Rasakriya and Churna[119].

कल्को रसक्रिया चूर्णः त्रिविधंप्रतिसारणम् ।।१३।।

अ.हृ.सू. २२/१३

पित्तरक्तविषागंतून् गंभरानपि च व्रणान् ।

रोपयेद्रोपणीयेन क्षीरसिध्देन सर्पिषा ।।

सु.चि. १-७०, ७१

रोध्रसर्जरसक्षौद्रमधुकैः प्रतिसारणम् ।

वा.उ. २१-६

यष्टीमधुकचूर्णंतु विदध्यात् प्रतिसारणम् ।।

सु.चि. २२/५

With reference to the present study, use of Ghruta in Mukha Pratisarana is beneficial as it has been described that the medicated ghee is useful to heal Vrana caused due to Pitta Dushti, Rakta Dushti, etc[120].

The Pittaghna and Vataghna dravyas used in Mukha Pratisarana help to relieve the symptoms like Daha, Paka, etc. and also help in better wound healing. It also helps to relieve the Hanugraha by reducing Stambha of the muscles of the jaw.

Nasya :

औषधम्औषधसिध्दंस्नेहोवा नासिकाभ्यां दीयते इति नस्यम् ।।

सु.चि. ४०-२१

ऊर्ध्वजत्रुविकारेषुविशेषान्नस्य मिष्यते ।

नासाहिशिरसोव्दारंतेन तद्व्याप्य हंतितात् ।।

अ.हृ.सु. २०/१

Nasa being the door way to Shira (head), the drug administered through nostrils, reaches Shringataka by Nasasrota and spreads in the Murdha (Brain) taking route of Netra (eye), Shrotra (ear), Kantha (throat), Siramukhas (opening of the vessels) etc. and scrapes the vitiated Doshas in supraclavicular region and extracts them from the Uttamanga.

Administration of medicine through this route is effective to treat diseases of that region.

न तस्य चक्षुर्नघ्राणंन श्रोत्रमुपहन्यते ।

न स्युः श्वेतानकपिलाः केशाः श्मश्रूणिवापुनः ।।५८।।

न च केशाः प्रमुच्यन्ते वर्धन्ते च विशेषतः ।

मन्यास्तम्भः शिरःशूलमर्दितंहनुसंग्रहः ।।५९।।

पीनसार्धनभेदौ च शिरःकम्पश्च शाम्यति ।

सिराः शिरःकपालानां सन्धयः स्नायुकण्डराः ।।६०।।

नावनप्रीणिताश्चस्य लभन्तेप्यधिकं बलम् ।

मुखंप्रसन्नोपचितंस्वरः स्निग्धःस्थिरोमहान् ।।६१।।

सर्वेन्द्रियाणां वैमल्यं बलंभवति चाधिकम् ।

न चास्य रोगाः सहसा प्रभवन्त्यूर्ध्वजत्रुजाः ।।६२।।

जीर्यतंश्चोत्तमांगेषुजरानलभतेबलम् ।

च.सू. ५/५८-६२

Benefits of Nasya[121] :

The healthy person who undergoes the Nasya Karma in suitable season with suitable drugs will never suffer from the impaired functions of eyes, nose, and ears. It will help to prevent falling of hair of scalp and beard and also graying of hair. It will stimulate the growth of scalp hair. It helps to nourish the Sira (veins), Sandhis (joints), Snayu (ligaments), Kandara (tendons) of the head and makes them strong. The person's face becomes cheerful and well developed (Mukha Prasannata). His voice will be melodious, Sthira (stable) Mahan (grave). It imparts Vaimalya (clarity) and Bala (strength) to all sense organs. It prevents the diseases of supra clavicular region of the body i.e. head and neck region.

Nasya Karma helps to cure conditions like Manya Stambha (torticolis), Shira Shula (headache), Ardita (facial paralysis), Hanu Sangraha (lock jaw, trismus), Ardhavabhedaka (migraine), Peenasa (chronic rhinitis), Shirakampa (tremor).

रुजावन्तोनिलाविष्टारुक्षा ये चोर्ध्वजत्रुजाः ।

व्रणेषुतेषु कर्तव्यं नस्यं वैद्येनजानता ।।

सु.चि. १/१२६

नस्यंस्नैहिकमेव ...डल्हण

नस्यं च तैलंवातघ्नमधुरस्कंधसाधितम् ।।

अ.ह्र.उ. २-१, २, ४

Nasya has been indicated in the Urdhwajatrugata Vrana which are mostly dry, painful and of the Vataja type. Here the term Nasya refers to Snehika Nasya. Use of Taila (oil) in Snehika Nasya for Vata – Kapha disorders. Various types of Sneha Dravya have been described according to Dosha predominance viz, Taila in Vata-Kapha Dushti, Vasa in Vata Dushti, Ghruta in Pitta Dushti and Majja in Pitta-Vata Dushti, use of Taila as Nasya Dravya can be considered in all the Dosha Dushti as 'Nasa' is the site of Kapha predominance.

तैलंकफेसवाते स्यात् केवलेपवनेवसाम् ।

दद्यात्सर्पिः सदापित्तेमज्जानं च समारुते ।।

चतुर्विधस्य स्नेहस्य विधिरेवंप्रकीर्तितः।

श्लेष्मस्थानाविरोधित्वात्तेषुतैलं विधीयते ।।

सु.चि. ४०/५६, ५७

Karnapurana :

Karnapurana is a procedure in which oil is instilled in the external ear and retained for a certain period. Acharya Vaghbhat has described the period to be of 100 Matra.

धारयेत्पूरणं कर्णेकर्णमूलं विमर्दयन्

रुजः स्थान्मार्दवं यावन्मात्राशतमवेदने ।। ३१ ।।

अ.हृ.सू. २२/३२

नकर्णरोगावातोत्थान मन्या हनुसंग्रहः ।

नोच्चैः श्रुतिर्नवाधिर्य स्यान्नित्यं कर्णतर्पणात् ।।

च.सू. ५/८४

हनुमन्याशिरःकर्णशूलघ्नंकर्णपूरणम् ।।

सु.चि. २४/२७

Regular practice of Karnapurana can help to prevent ear diseases due to Vata, stiffness at neck, back and jaw region, deafness and hearing impairment[122].

वातस्योपक्रमः स्नेहः स्वेदः संशोधनं मृदु ।

अ.हृ.सू. १३/१

Use of Sneha in various forms has been described by Acharya Vaghbhat to pacify the Vata[123]. Hence the various procedures included in the present study like Snehana, Swedana along with Matra Basti, Nasya, Gandusha, Mukha Pratisarana, Shirodhara and Karnapurana help to pacify the vitiated Vata Dosha.

C) DRUG REVIEW :

Cancer being one of the most dreadful diseases of the present era, various researches have been done and are going on its gene and molecular level, many treatment modalities have been explored, but success is still far. However, in contrast to classical medicine that has existed for thousands of years from the time of Vedas, many herbs and formulations have been described which not only useful for the treatment but also promote good health and longevity without any side-effects to mankind.

In the present study, the oral cavity cancer patients of both groups (study and control) are receiving oral Ayurvedic medicines. In study group, along with oral Ayurvedic medicines, combination of Panchakarma procedure like Basti and Nasya along-with some allied procedures like Gandusha, Mukha Pratisarana, Shirodhara and Karnapurana have been administered to the patient. This is done to observe the add-on effect of Panchakarma and allied procedures on the disease status and quality of life of these cancer patients.

The drugs which are used for these procedures mostly possess anti-inflammatory, anti-oxidant, anti-septic and anti-cancer properties. The main principle in designing the treatment protocol is pacification of vitiated Doshas which are mainly due to treatment modalities like surgery, radiation and chemotherapy; rejuvenate body functions; restore immunity and improve quality of life.

For achieving this, the drugs basically acting on Vata Dosha, Pitta Dosha and Kapha Dosha possessing Madhur, Kashaya, Tikta Rasa, mainly Sheeta Virya and Snigdha Guna have been selected. The expected karma to be achieved is Vata Shamana, Vrana Ropana, Daha Shamana, Pitta Shamana, Kapha Shamana, Rakta Prasadana and to control Dhatugata and Dhatupaka Awastha.

Of the total drugs selected for Panchakarma and other allied procedures in the present study, Bala Taila is a classical preparation from Sushrut Samhita and is prepared in the Ayurvedic Pharmacy, Atharva Nature Healthcare whereas Dashmoola Taila, Yashtimadhu Ghruta, Yashtimadhu Taila and Atharva Gandusha Churna are the proprietary preparations of this pharmacy.

1. Bala Taila[128] :

Fig. 22 : Photo of Bala

बलामूलकषायस्य दशमूलीश्रृतस्य च ।।

यवकोलकुलत्थानां काथस्य पयसस्तथा ।

अष्टावष्टौ शुभा भागास्तैलादेकस्तदेकतः ।।

पचेदावाप्य मधुरं गणं सैन्धवसंयुतम् ।

तथाऽगुरुं सर्जरसं सरलं देवदारु च ।।

मंजिष्ठां चन्दनं कुष्ठमेलां कालानुसारिवाम् ।

मांसीं शैलेयक पत्रं तगरं सारिवां वचाम् ।।

शतावरीमश्वगन्धां शतपुष्पां पुनर्नवाम् ।

तत् साधुसिध्दं सौवर्णे राजते मृन्मयेऽपि च ।।

प्रक्षिप्य कलशे सम्यक् स्वनुगुत्पं निघापयेत् ।

बलातैलमिदं ख्यातं सर्ववातविकारनुत् ।।

यथाबलमतो मात्रां सूतिकायै प्रदापयेत् ।

या च गर्भार्थिनी नारी क्षीणशुक्रश्च यः पुमान् ।।

वातक्षीणे मर्महते मथितेभिहते तथा ।

भग्ने श्रमाभिपन्ने च सर्वथैवोपयुज्यते ।।

एतदाक्षेपकादीन् वै वातव्याधिमपोहति ।

हिक्कां कासमधीमन्थं गुल्मं श्वास च दुस्तरम् ।।

षण्मासानुपयुज्यैदन्त्रवृध्दिमपोहति ।

प्रत्यग्रधातुः पुरुषो भवेच्च स्थिरयौवनः ।।

राज्ञामेतध्दि कर्तव्यं राजमात्राश्च ये नराः ।

सुखिनः सुकुमाराश्च धनिनश्चपि ये नराः ।।

सु.चि. १५/२९-३९

Table 12 : Details of contents of Bala Taila

Sr. No.	Dravya name	Latin name	Rasa (Taste)	Veerya (Potency)	Vipaka (Post-digestive effect)	Doshaghnata (Action on Doshas)	Karma (Action)
1	Bala	*Sida cordifolia*	Madhur	Sheeta	Madhur	Vata-Pittahara	Balya, Vrushya, Bruhana, Sangrahi
2	Dashmoola		Kashaya, Tikta, Madhur	Ushna	Katu	Tridoshaghna	Pachana, Deepana
3	Yava	*Hordeum vulgare*	Madhur	Sheeta	Katu	Kapha-Pitta Shamaka, Vatavardhaka	Medoghna, Balya, Sthairyakrit
4	Kola	*Zizhipus mauritiana*	Madhur Amla Kashaya	Ushna	Madhur	Vatanashaka	Hrudya, Grahi, Rochana
5	Kulatha	*Dolichos biflorus*	Kashaya Amla	Ushna	Katu	Kapha-Vatashamaka	Lekhan, Mutral, Ashmarighna
6	Godugdha	Cow's milk	Madhur	Sheeta	Madhur	Vata-Pitta hara, Kaphavardaka	Rasayan Medhya, Vrushya, Balya, Bruhana
7	Saindhav	Rock salt	Lavan	Anushna	Madhur	Tridoshaghna	Deepana, Pachana, Vrushya, Netrya,
8	Agaru	*Aquilariaa gallocha*	Tikta Katu Kashaya	Ushna	Katu	Kapha-Vata nashak	Netrya
9	Sarjaras	*Shorea robusta*	Tikta Kashaya	Sheeta	Katu	Kapha-Pitta nashaka	Vednasthapan Sandhaniya
10	Saral	*Pinus longifolia*	Katu Tikta Madhua	Ushna	Katu	Kapha-Vatahara	Vranaropana, Rakshoghna
11	Devdaru	*Cedrus deodar*	Tikta	Ushna	Katu	Kapha-Vatanashak	Deepana, Kasahara

Sr. No.	Dravya name	Latin name	Rasa (Taste)	Veerya (Potency)	Vipaka (Post-digestive effect)	Doshaghnata (Action on Doshas)	Karma (Action)
12	Manjishtha	*Rubia cordifolia*	Madhur, Tikta Kashaya	Ushna	Katu	Kapha-Vatashamaka	Varnya, Swarya, Vishaghna, Rakta Prasadana
13	Chandan	*Santalum alba*	Tikta	Sheeta	Katu	Kapha-Pitta Shamaka	Aalhadan, Dahashamak, Grahi, Trushnashamak, Vishaghna, Rakta Prasadak, Mutral, Varnya, Kapha Nisarak
14	Kushtha	*Saussurea Lappa*	Tikta Katu Madhur	Ushna	Katu	Kapha-Vatashamaka	Kapha Nisarak, Shoola Prashaman, Jantughna
15	Ela	*Elletaria cardamom*	Madhur	Sheeta	Madhur	Vatahara	Sushma
16	Jatamansi	*Valeriana jatamansi*	Tikta, Kashaya Madhur	Sheeta	Madhur	Tridosha Shamaka	Kanti-Balaprada, Medhya,
17	Shaileyaka	*Parmelia perlata*	Tikta Kashaya	Sheeta	Katu	Kapha-Pittahara	Hrudya
18	Patra - Tamalpatra	*Cinnamomum tamala*	Madhur Katu Tikta	Ushna	Madhur	Kapha-Vatahara	Deepana, Ruchya, Swedajanan,
19	Tagar	*Valeriana wallichi*	Tikta Katu Kashaya	Ushna	Katu	Tridoshaghna Kapha-Vatahar	Vishaghna
20	Sariva	*Hemidesmus indicus*	Madhur, Tikta	Sheeta	Madhur	Tridoshaghna	Vrushya, Raktaprasadak, Deepana, Pachana,

Sr. No.	Dravya name	Latin name	Rasa (Taste)	Veerya (Potency)	Vipaka (Post-digestive effect)	Doshaghnata (Action on Doshas)	Karma (Action)
							Dahanashak
21	Vacha	*Acorus calamus*	Tikta Katu	Ushna	Katu	Kapha-Vatahara	Lekhana, Asthapana, Sheeta Prashaman, Sajnyasthapan
22	Shatavari	*Asparagus racemosus*	Madhur Tikta	Sheeta	Madhur	Vata-Pitta shamaka	Rasayana, Vrushya
23	Ashwagandha	*Withania somnifera*	Madhur Tikta Kashaya	Ushna	Madhur	Kapha-Vatahara	Shukravardak, Rasayan, Balya
24	Shatapushpa	*Anethum sowa*	Katu Tikta	Ushna	Katu	Kapha-Vatahara	Deepana, Pachana, Vatanulomana
25	Punarnava	*Boerrhavia diffusa*	Madhur Tikta Kashaya	Ushna	Madhur	Tridoshahara	Deepana Pachana, Lekhan, Mutrajanan, Anulomana, Rasayan Vishaghna
26	Til Taila	*Sesamum indicum*	Katu Tikta Kashaya Madhur	Ushna	Katu	Vatahara	Twachya, Balya, Keshya, Rasayan

2. Dashmoola[129] Bharad :

Fig. 23 : Photo of Dashmoola

Table 13 : Details of contents of Dashmoola Bharad

Sr. No.	Dravya	Latin name	Rasa	Veerya	Vipaka	Doshaghnata	Karma
1	Bilva	*Aegle marmelos*	Kashaya	Ushna	Katu	Vata-Kaphahara	Pittakara, Balya, Grahi, Deepana - Pachana
2	Agnimantha	*Premna integrifolia*	Tikta Katu Kashaya	Ushna	Katu	Vata Shaman	Deepana, Pchana, Anulomana, Vedanasthapan
3	Shyonaka	*Oroxylum indicum*	Tikta Kashaya Madhur	Ushna	Katu	Kapha-Vata Shamak, Tridoshaghna	Deepana
4	Patala	*Stereospermum suaveolens*	Kashaya Tikta	Anushna	Katu	Tridosha Shamak	Vishaghna Shothaghna
5	Gambhari	*Gmelina arborea*	Tikta Kashaya Madhur	Ushna	Katu	Vata-Kaphahara	Deepana, Pachana, Medya, Mala bhedak
6	Shaliparni	*Desmodium gangeticum*	Madhur, Tikta	Ushna	Madhur	Tridosha-shamak	Bruhana, Rasayan
7	Prishniparni	*Uraria picta*	Madhur Tikta	Ushna	Madhur	Tridosha-shamak	Vrushya, Angmarda Prashaman, Sandhaneeya, Shothahara

Sr. No.	Dravya	Latin name	Rasa	Veerya	Vipaka	Doshaghnata	Karma
8	Vartaki	*Solanum indicum*	Katu Tikta	Ushna	Katu	Kapha-Vatashamak	Hrudya, Pachana, Rechana
9	Kantkari	*Solanum suratens*	Tikta Katu	Ushna	Katu	Kapha-Vatashamak	Deepana, Pachana, Mutral, Kantya, Malabhedan
10	Gokshur	*Tribulus terrestris*	Madhur	Sheeta	Madhur	Vata-Pittashamak	Kaphavardaka, Mutral, Balya, Bastishodhak, Vrushya, Deepana

3. Dashmoola[129] Taila :

Table 14 : Details of contents of Dashmoola Taila

Sr. No.	Dravya	Latin name	Rasa	Veerya	Vipaka	Doshaghnata	Karma
1	Bilva	*Aegle marmelos*	Kashaya	Ushna	Katu	Vata-Kaphahara	Pittakara, Balya, Grahi, Deepana - Pachana
2	Agnimantha	*Premna integrifolia*	Tikta Katu Kashaya	Ushna	Katu	Vata Shaman	Deepana, Pachana, Anulomana, Vedanasthapan
3	Shyonaka	*Oroxylum indicum*	Tikta Kashaya Madhur	Ushna	Katu	Kapha-Vata Shamak Tridoshaghna	Deepana
4	Patala	*Stereospermum suaveolens*	Kashaya Tikta	Anushna	Katu	Tridosha shaman	Vishaghna Shothaghna
5	Gambhari	*Gmelina arborea*	Tikta Kashaya Madhur	Ushna	Katu	Vata-Kaphahara	Deepana, Pachana, Medya, Mala bhedak
6	Shaliparni	*Desmodium gangeticum*	Madhur, Tikta	Ushna	Madhur	Tridosha shamak	Bruhana, Rasayan
7	Prishniparni	*Uraria picta*	Madhur Tikta	Ushna	Madhur	Tridosha shamak	Vrushya, Angamarda Prashaman, Sandhaneeya, Shothahara
8	Vartaki	*Solanum indicum*	Katu Tikta	Ushna	Katu	Kapha-Vatashamak	Hrudya, Pachana, Rechana
9	Kantkari	*Solanum suratens*	Tikta Katu	Ushna	Katu	Kapha-Vatashamak	Deepana, Pachana, Mutral, Kantya, Malabhedan
10	Gokshur	*Tribulus terrestris*	Madhur	Sheeta	Madhur	Vata-Pitta shamak	Kaphavardak, Mutral, Balya, Bastishodhak, Vrushya, Deepana
11.	Til Taila	*Sesamum indicum*	Katu Tikta Kashaya Madhur	Ushna	Katu	Vatahara	Twachya, Balya, Keshya, Rasayan

4. Atharva Gandusha Churna[130,131]:

Fig. 24 : Photo of Triphala

Fig. 25 : Photo of Haridra

Table 15 : Details of contents of Atharva Gandusha Churna

Sr. No.	Dravya	Latin name	Rasa	Veerya	Vipaka	Doshaghnata	Karma
1	Haritaki	*Terminalia chebula*	Kashaya pradhan Pancha rasa, Lavanvarjit	Ushna	Madhur	Tridoshaghna	Rasayan, Netrya, Anulomana, Bruhana
2	Bibhitaka	*Terminalia belerica*	Kashaya	Ushna	Madhur	Tridoshahara Kaphashamak	Bhedana, Netrya, Keshya, Chedana, Krimighna
3	Aamalaki	*Emblica officinalis*	Amla pradhan Pancha rasa	Sheeta	Madhur	Tridoshaghna	Deepana, Pachana, Anuloman, Mrudu Virechana
4	Haridra	*Curcuma longa*	Katu Tikta	Ushna	Katu	Kapha-Vatashamak	Vednasthapana, Rakta Prasadan, Pachana, Vishaghna, Varnya, Lehana

5. Yashtimadhu[132] Ghruta :

Fig. 26 : Photo of Yashtimadhu

Table 16 : Details of contents of Yashtimadhu Ghruta

Sr. No.	Dravya	Latin name	Rasa	Veerya	Vipaka	Doshaghnata	Karma
1	Yastimadhu	*Glycyrrhiza glabra*	Madhur	Sheeta	Madhur	Vata-Pitta shaman	Chakshushya, Balya, Varnya, Sandhaneeya
2	Goghrut	Cow's ghee	Madhur	Sheeta	Madhur	Vata-Pitta shaman	Vrushya, Deepana, Chakshushya, Rasayan, Balya, Vayasthapan

6. Yashtimadhu[132] Taila :

Table 17 : Details of contents of Yashtimadhu Taila

Sr. No.	Dravya	Latin name	Rasa	Veerya	Vipaka	Doshaghnata	Karma
1	Yastimadhu	*Glycyrrhiza glabra*	Madhur	Sheeta	Madhur	Vata-Pitta shaman	Chakshushya, Balya, Varnya, Sandhaneeya
2	Til Taila	*Sesamum indicum*	Katu Tikta Kashaya Madhur	Ushna	Katu	Vatahara	Twachya, Balya, Keshya, Rasayan

7. Jatamansi[133] Taila :

Fig. 27 : Photo of Jatamansi

Table 18 : Details of contents of Jatamansi Taila

Sr. No.	Dravya	Latin name	Rasa	Veerya	Vipaka	Doshaghnata	Karma
1	Jatamansi	*Valeriana jatamansi*	Tikta, Kashaya Madhur	Sheeta	Madhur	Tridosha shamak	Kanti-Balaprada, Medhya,
2	Til Taila	*Sesamum indicum*	Katu Tikta Kashaya Madhur	Ushna	Katu	Vatahara	Twachya, Balya, Keshya, Rasayan

MATERIALS AND METHODS

Source of literature :

All the Ayurvedic literature and information available about oral cancers from books, articles and journals of allopathic system of medicine as well as Samhitas, text books and journals from Ayurveda were referred as literature resources. Websites and abstracts available online were also referred.

Source of medicines :

The raw materials and finished products needed in the study were obtained from Bharatiya Sanskriti Darshan Trust's Atharva Nature Healthcare Pvt. Ltd. The authentication of the raw materials as well as standardization of finished products was duly carried out by the pharmacy which is a FDA approved and GMP certified pharmacy. Certificate of Analysis for the required drugs are attached as appendices.

Grouping of the patients :

Patients of oral cavity cancers were selected from the Oncology OPDs of BSDT's Integrated Cancer Treatment and Research Center's Pune and Mumbai centers. Male as well as female patients were selected following the predesigned inclusion and exclusion criteria.

200 patients of oral cavity cancer who were taking Shamana Chikitsa at the study center were examined. Out of them, 70 patients were selected with similar stage, grade, conventional treatment and duration of Ayurvedic treatment. All the 70 patients were eligible for Panchakarma and for the purpose of the present study, two groups of 35 patients each for the study group and control group respectively were enrolled. In both the group, the Shamana Chikitsa mainly comprised :

1. Morning – Evening : Vasadi Vati 1500 mg + Mouktikayukta Kamdudha 500 mg with lukewarm water.
2. Before lunch and dinner : Yashtimadhu Ghruta 5 mg with lukewarm water.
3. After lunch and dinner : Sukshma Triphala 500 mg + Triphala Guggulu 500 mg with lukewarm water.

Study Design:

1. The present study is a case control study. The two groups were as follows -

A. 'Study group = 35 patients of oral cavity cancer treated with 7 days of Basti, Nasya, Gandusha, Mukhapratisarana, Shirodhara and Karnapurana along-with Shamana Chikitsa and who had completed conventional treatment.

B. 'Control group = 35 patients of oral cavity cancer who were treated with only 'Shamana Chikitsa' and had completed conventional treatment. They were not given Basti, Nasya, Gandusha, Mukhapratisarana, Shirodhara and Karnapurana.

2. Inclusion criteria :

1) Oral cavity cancer patients of all stages who had received surgery.
2) Oral cavity cancer patients of all stages who had received radiation therapy.
3) Oral cavity cancer patients of all stages who had received radiation therapy along with concurrent chemotherapy.
4) Male and female patients from age group of 20 years to 85 years.

3. Exclusion criteria :

Oral cavity cancer patients other than squamous cell carcinoma.

4. Consent form :

Once the patient was allocated in the respective groups informed consent of patients was taken.

5. Case Record Form (CRF) :

Case taking in both the groups was done as per the pre-designed CRF.

6. Assessment Criteria:

In both the groups, assessment was done at three time points –

For Study Group:

a. before starting the treatment,
b. after completion of treatment i.e. 7^{th}day
c. one month after completion of the treatment.

For Control group : The time points 'a', 'b' and 'c' for Control group patients having only Shamana Chikitsa corresponds with time point 'a', 'b' and 'c' of study group respectively

a. Scoring of symptoms :

The scoring of symptoms is done on basis of CTCAE 4.03[124].

Common Terminology Criteria for Adverse Events (CTCAE) is widely accepted throughout the oncology community as the standard classification and severity grading scale for adverse events in cancer therapy clinical trials and other oncology settings.

For the present study symptoms like stomatitis (Mukhapaka), trismus (Hanugraha), xerostomia (Talushosha), excessive salivation (Atyadika Lalasrava), dysphagia (Anna-nirgalana Kashtatva), foul smell of mouth (Putimukha), debility (Daurbalya) and pain (Shoola) were considered.

Table 19 : Scoring of symptoms on basis of CTCAE 4.03

Sr. No.	Symptom	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
1	Stomatitis	No symptom noted.	Patient has erythema of the mucosa.	Patient has ulceration in patches with pseudomembranes.	Patients has ulceration which bleeds with minor trauma.	Patient has tissue necrosis, significant spontaneous bleeding.
2	Xerostomia	No symptom noted.	Xerostomia is only symptomatic. No need of dietary alteration. Unstimulated saliva flow present.	Xerostomia is symptomatic and significant oral intake alteration with unstimulated saliva.	Xerostomia leading to inability to take orally. Tube feeding required. Saliva is unstimulated.	-
3	Loss of Taste	No symptom noted.	Taste is altered but no change in diet required.	Taste is altered and change in diet required.	-	-
4	Extensive Salivation	No symptom noted.	Patient has slightly thickened saliva and slightly altered taste.	Patient has thick and sticky saliva, markedly altered taste. Alteration of diet is indicated.	Patient has severe secretions. Symptoms interfering with ADL.	Disabling.
5	Trismus (difficulty in opening of mouth)	No symptom noted.	Patient has decreased motion of jaw. Patient cannot open for more than 4 cm.	Patient's motion of jaw decreased and required small bites, soft foods or purees. Patient cannot open for more than 3 cm.	Severe restriction of jaw. Inability to hydrate orally. Patient cannot open for more than 2 cm.	Patient cannot open for more than 1 cm.

Sr. No.	Symptom	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
6	Dysphagia	No symptom noted.	Dysphagia is symptomatic but able to eat regular diet.	Dysphagia is symptomatic but altered dietary habits. IV fluids indicated in <24 hrs.	Dysphagia is symptomatic and severely altered eating / swallowing required IV fluids /tube feedings / TPN indicated in ≥24 hrs.	Life threatening consequences like obstruction, perforation.
7	Nausea	No symptom noted.	Patient has nausea with loss of appetite without alteration in eating habits.	Oral intake of patient decreased without significant weight loss, but IV fluids indicated < 24 hrs.	Oral caloric or fluid intake is less , tube feeding required , TPN indicated ≥24 hrs	Due to Nausea life-threatening consequences happen.
8	Local pain	Mild pain not interfering with function.	Moderate pain; pain or analgesics interfering with function, but not interfering with ADL.	Severe pain; pain or analgesics severely interfering with ADL.	Disabling.	-
9	Tinnitus	-	Tinnitus not interfering with ADL.	Tinnitus interfering with ADL.	Disabling.	-
10	Weight Loss	Weight loss is less than 5 % weight loss from baseline.	Weight loss is 5 to <10% from baseline which do not required intervention.	Weight loss is 10 – <20% from baseline. Required nutritional support.	Weight loss is ≥20% from baseline and needs tube feeding or TPN.	-

b. EORTC QLQ-C30 :

The European Organization for Research and Treatment of Cancer Quality of Life questionnaire (EORTC QLQ-C30) is an integrated system for assessing the Quality of Life (QoL) of cancer patients participating in clinical trials and other types of research in which patient-reported outcomes are collected[125].

The EORTC QLQ-C30 is designed for use with a wide range of cancer patient populations and is intended to be supplemented by tumor-specific questionnaire modules or supplements such as those for lung cancer (QLQ-LC13), breast cancer (QLQ-BR23), head and neck cancer (QLQ-H&N35), oesophageal cancer (QLQ-OES18) and ovarian cancer (QLQ-OV28).

Table 20 : Scoring of QLQ-C30 version 3.0

	Scale	**Number of items**	**Version 3.0 Item numbers**
Global health status / QoL			
Global health status/QoL (revised)	QL2	2	29,30
Functional scales			
Physical functioning (revised)	PF2	5	1 to 5
Role functioning (revised)	RF2	2	6, 7
Emotional functioning	EF	4	21 to 24
Cognitive functioning	CF	2	20, 25
Social functioning	SF	2	26, 27
Symptom scales / items			
Fatigue	FA	3	10, 12, 18
Nausea and vomiting	NV	2	14, 15
Pain	PA	2	9, 19
Dyspnoea	DY	1	8
Insomnia	SL	1	11
Appetite loss	AP	1	13
Constipation	CO	1	16
Diarrhoea	DI	1	17
Financial difficulties	FI	1	28

c. Head & Neck cancer module: QLQ-H&N35 :

The head & neck cancer module is meant for use among a wide range of patients with head & neck cancer, varying in disease stage and treatment modality (i.e. surgery, radiotherapy and chemotherapy). The module comprises 35 questions assessing symptoms and side effects of treatment, social function and body image / sexuality[125].

The head & neck cancer module incorporates seven multi-item scales that assess pain, swallowing, senses (taste and smell), speech, social eating, social contact and sexuality. There are also eleven single items. For all items and scales, high scores indicate more problems (i.e. there are no function scales in which high scores would mean better functioning). The scoring approach for the QLQ-H&N35 is identical in principle to that for the symptom scales / single items of the QLQ-C30.

Table 21 : Scoring of QLQ-H&N35

	Scale	Number of items	QLQ-H&N35 Item numbers
Pain	HNPA	4	1-4
Swallowing	HNSW	4	5-8
Senses problems	HNSE	2	13,14
Speech problems	HNSP	3	16,23,24
Trouble with social eating	HNSO	4	19-22
Trouble with social contact	HNSC	5	18,25-28
Less sexuality	HNSX	2	29,30
Teeth	HNTE	1	9
Opening mouth	HNOM	1	10
Dry mouth	HNDR	1	11
Sticky saliva	HNSS	1	12
Coughing	HNCO	1	15
Felt ill	HNFI	1	17
Pain killers	HNPK	1	31
Nutritional supplements	HNNU	1	32
Feeding tube	HNFE	1	33
Weight loss	HNWL	1	34
Weight gain	HNWG	1	35

d. Karnofsky Performance Status Scale :

The Karnofsky Performance Scale Index is an assessment tool for functional impairment. It can be used to compare effectiveness of different therapies and to assess the prognosis in individual patients. In most serious illnesses, the lower the Karnofsky score, the worse the likelihood of survival[126].

Table 22 : Karnofsky Performance Status Scale

Karnofsky Status	Karnofsky Grade	ECOG Grade	ECOG Status
Normal, no complaints	100	0	Fully active, able to carry on all pre-disease performance without restriction
Able to carry on normal activities. Minor signs or symptoms of disease	90	1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
Normal activity with effort	80	1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
Care for self. Unable to carry on normal activity or to do active work	70	2	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
Requires occasional assistance, but able to care for most of his needs	60	2	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
Requires considerable assistance and frequent medical care	50	3	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
Disabled. Requires special care and assistance	40	3	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours

Karnofsky Status	Karnofsky Grade	ECOG Grade	ECOG Status
Severely disabled. Hospitalization indicated though death non-imminent	30	4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
Very sick. Hospitalization necessary. Active supportive treatment necessary	20	4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
Moribund	10	4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
Dead	0	5	Dead

e. Pain Assessment :

Pain intensity is a common outcome domain assessed in pain clinical trials and most often targeted in pain treatment. Pain intensity is commonly assessed using measures such as the Visual Analogue Scale (VAS), Numerical Rating Scale (NRS), Verbal Rating Scale (VRS), and Faces Pain Scale-Revised (FPS-R). In the present study we have used Numerical Rating Scale (NRS)[127].

The 11-point NRS consists of numbers between 0 and 10 where

0 - No pain.

10 - Maximum pain.

The respondent is instructed to identify one number between 0 and 10, which is best representative of their pain intensity.

Time points for Study and Control Groups :

For Study group :

a. Before starting Basti, Nasya, Gandusha, Mukhapratisarana, Shirodhara and Karnapurana.
b. At the end of treatment.
c. 1 month after the treatment.

For Control Group :

a. Corresponds to Day '0' as in study group
b. 7th day of 'Shamana Chikitsa' corresponding to time point 'b' of study group.
c. 1 month after 'Shamana Chikitsa' corresponding to time point 'c' of study group.

Table 23 : Treatment Protocol for Study Group

Sr. No.	Procedure	Drug administered	Quantity / Dose	Duration	Position of patient
1	Sarvang Snehana	Bala Taila	50 ml	About 25 minutes	Prone and supine position
2	Sarvang Swedana	Dashmoola Bharad	250 gms in 5 litres of water	About 12 minutes	Sitting / Supine position
3	Matra Basti	Dashmoola Taila	50 ml	------	Left lateral position
4	Nasya	Yashtimadhu Taila	4 drops in each nostril	------	Supine position, head slightly tilted backward
5	Mukha Pratisarana	Yashtimadhu Ghruta	10 ml	2 minutes	Sitting position
6	*Gandusha	Atharva Gandusha Churna	200 ml	5 minutes	Sitting position
7	Shirodhara	Jatamansi Taila	500 ml	10 minutes	Supine position.
8	Karnapurana	Dashmoola Taila	2 ml in each ear		Left lateral position for Right ear. Right lateral position for Left ear.

***Preparation of Gandusha – 1 part Gandusha Churna mixed with 64 parts of water boiled till the water quantity reduces to half, filter the decoction in a glass and used for gargling.**

Treatment duration:

The intervention of the study group treatment protocol was done at three time points. Assessment of the effect of the treatment was done before treatment, at the end of treatment and 1 month after the treatment.

Statistical analysis:

The data collected during the clinical study was tabulated and statistically analyzed using Man Whitney Z test, t test and statistical methods like parametric, non-parametric and ANOVA. The probability of $p<0.05$ was considered significant.

ANALYSIS

The study was conducted on 70 patients of cancers of oral cavity. These patients were selected from the Oncology OPDs of Bharatiya Sanskriti Darshan Trust's Integrated Cancer Treatment and Research Center's Pune and Mumbai centers.

Patients were divided in 2 groups viz Study group consisting of 35 patients of oral cavity cancer treated with 7 days of Basti, Nasya, Mukhopakrama, Shirodhara and Karnapurana along-with Shamana Chikitsa and who have completed conventional treatment. Control group consisting of 35 patients of oral cavity cancer who are treated with only Shamana Chikitsa and have completed conventional treatment. They were not given Basti, Nasya, Mukhopakrama, Shirodhara and Karnapurana.

On the basis of observations, data collected was divided into :

A. Demographic data
B. Clinical data (mainly symptoms and Quality of Life)

A. Demographic Data :

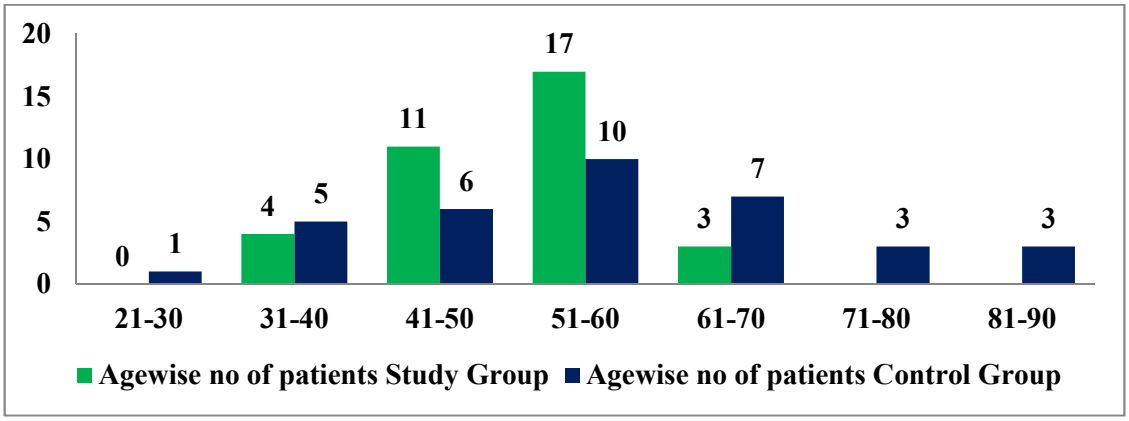
Demographic data consisted of age-wise, sex-wise, socio-economic wise, status stage-wise, grade-wise, conventional treatment taken and site-wise distribution of patients.

1. Observations based on age of patients of oral cavity cancer :

Table 24 : Age-wise distribution of patients of oral cavity cancer

Age Group in Yrs.	Study Group		Control Group	
	No. of patients	%	No. of patients	%
21-30	0	0	1	2.7
31-40	4	11.43	5	14.29
41-50	11	31.43	6	17.14
51-60	17	48.57	10	28.57
61-70	3	8.57	7	20
71-80	0	0	3	8.57
81-90	0	0	3	8.57
Total no. of patients	**35**		**35**	

Graph 1 : Age-wise number of patients



In our study maximum number of patients lie in the age group 41 to 70 years in both the study and control group. Out of 35 patients from the study group, 31 patients were from

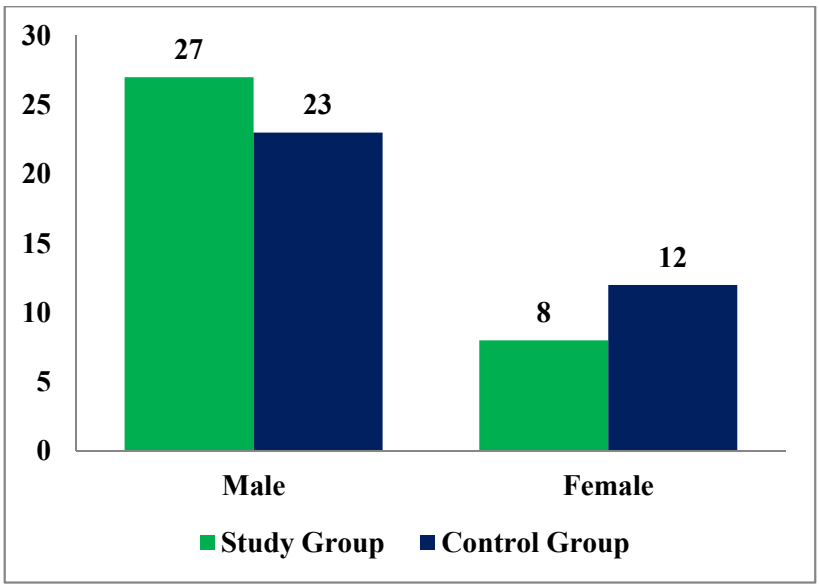
the age group 41 to 70 years constituting 88.57 %. Of 35 patients from the control group 23 patients were from the age group 41 to 70 years constituting 65.71 %.

2. Observations based on sex of patients of oral cavity cancer :

Table 25 : Distribution of patients of oral cavity cancer on basis of sex

Sex	Study Group		Control Group	
	No. of patients	%	No. of patients	%
Male	27	77.14	23	65.71
Female	8	22.85	12	34.28

Graph 2 : Number of patients according to sex



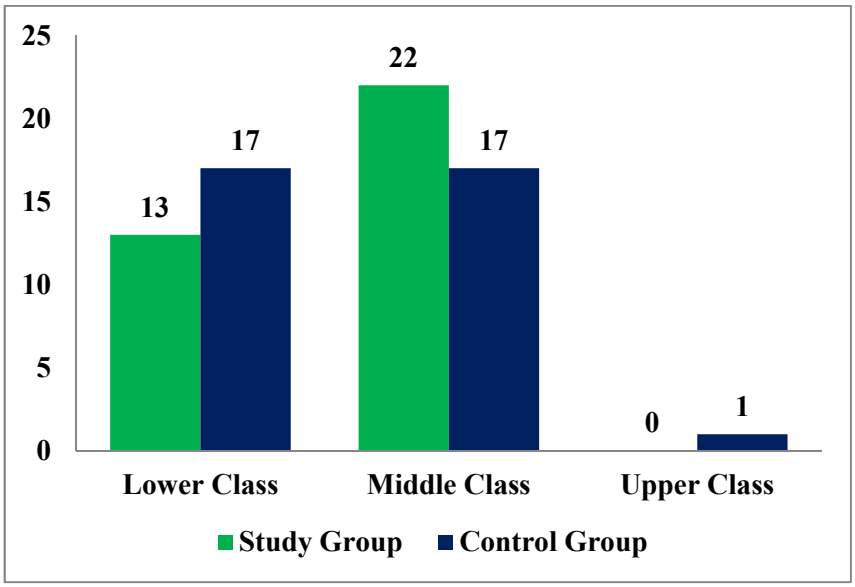
In our study maximum number of patients were males. Out of 35 patients from the study group 27 patients were males constituting 77.14 % and 8 patients were females constituting the rest of 22.85 %. Out of 35 patients from the control group 23 patients were males constituting 65.71 % and 12 patients were females constituting the rest of 34.28 %.

3. Observations based on socio-economic class of patients of oral cavity cancer :

Table 26 : Distribution of oral cavity cancer patients on basis of socio-economic class

Socio-economic status	Study Group		Control Group	
	No. of patients	%	No. of patients	%
Lower Class	13	37.14	17	48.57
Middle Class	22	62.85	17	48.57
Upper Class	0	0	1	2.85

Graph 3 : Number of patients according to socio-economic status



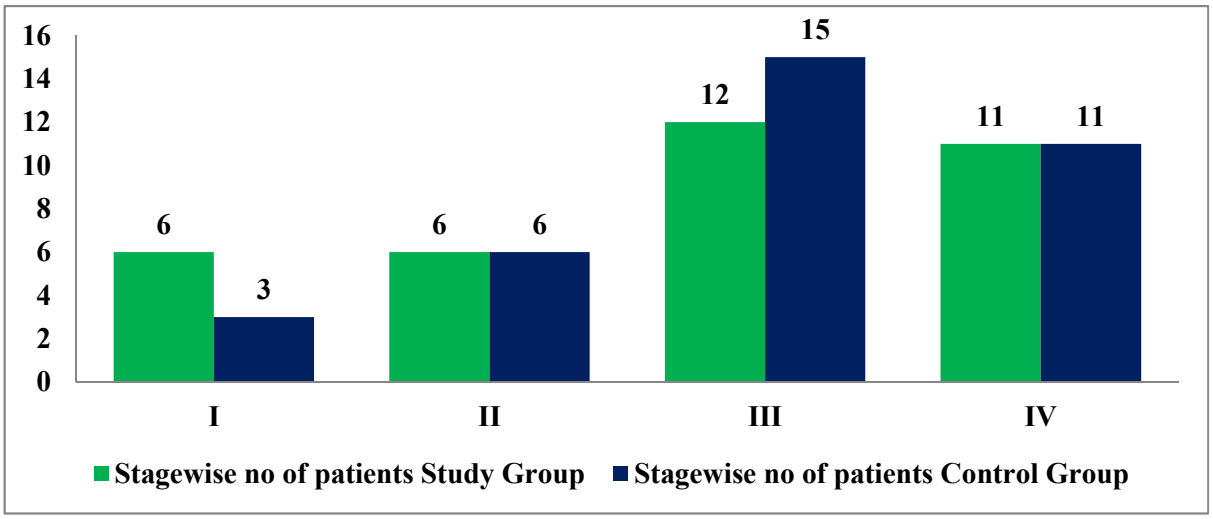
In our study maximum number of patients i.e. 22 patients were from middle socio-economic strata followed by 13 patients from lower socio-economic strata in study group. In control group, there was an equal distribution of patients from the middle as well as the lower socio-economic strata with 17 each respectively. Only 1 patient was observed to be from the upper socio-economic strata in control group.

4. Observations based on stage of cancer in patients of oral cavity cancer :

Table 27 : Stage-wise distribution of patients of oral cavity cancer

Stage of Cancer	Study Group		Control Group	
	No. of patients	%	No. of patients	%
I	6	17.14	3	8.57
II	6	17.14	6	17.14
III	12	34.28	15	42.86
IV	11	31.43	11	31.43
Total no. of patients	**35**		**35**	

Graph 4 : Number of patients according to stage



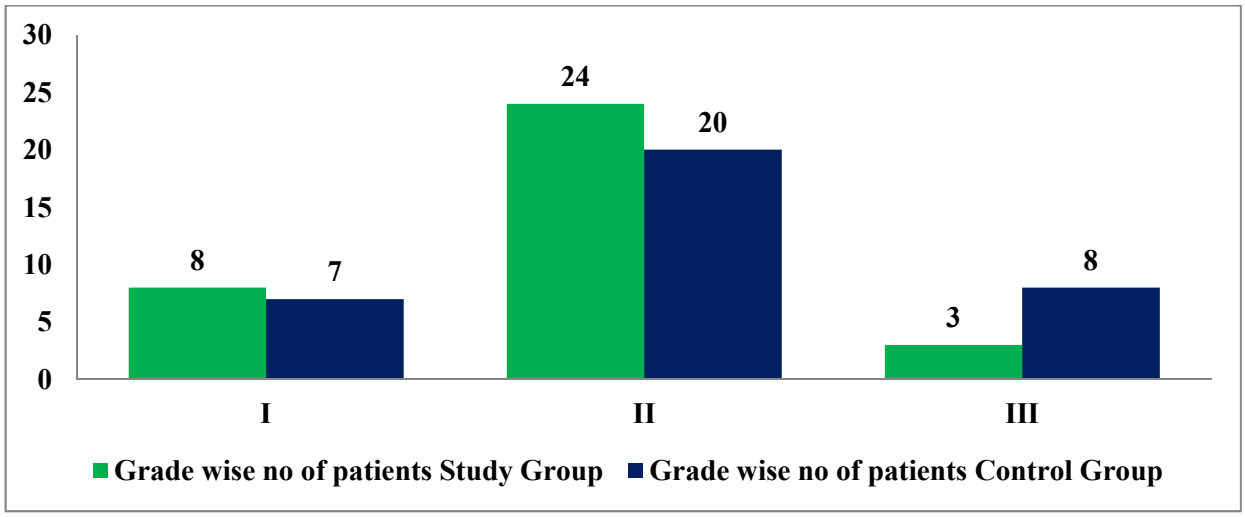
AJCC Cancer Staging manual (8th Ed) was used to determine stage of oral cavity cancers. It is divided in stage 0 to stage IV disease based on TNM Classification. In our study maximum number of patients were in stage III and stage IV disease in both the groups. 11 patients (31.43%) each had stage IV disease in both study and control group. 12 patients from study group (34.28%) and 15 patients (42.86%) from control group had stage III cancer. Stage II cancer was present in 6 patients (17.14%) each in study and control group. 6 patients (17.14 %) from study Group and 3 patients from control group (8.57%) had stage I cancer.

5. Observations based on grade of cancer in patients of oral cavity cancer :

Table 28 : Grade-wise distribution of patients of oral cavity cancer

Grade of Cancer	Study Group		Control Group	
	No. of patients	%	No. of patients	%
I	8	22.86	7	20
II	24	68.57	20	57.14
III	3	8.57	8	22.86
Total no. of patients	**35**		**35**	

Graph 5 : Number of patients according to grade



Grading of oral cancer is done on the basis of how different the cancer cells 1ook from normal cells. They are graded from grade I to III i.e. well differentiated, moderately differentiated and poorly differentiated cancer.

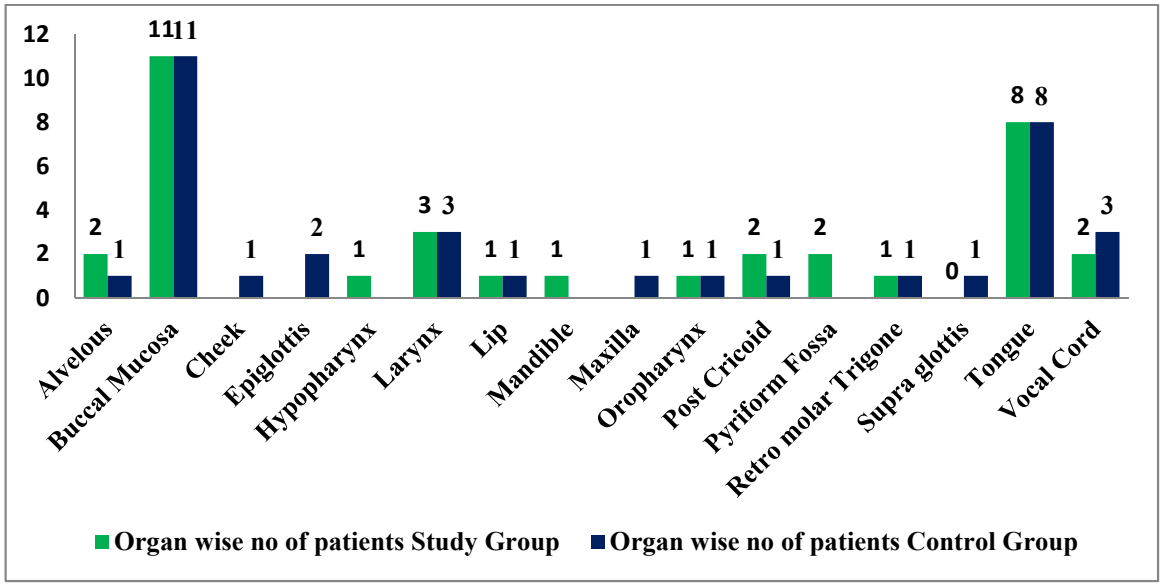
In our study maximum number of patients were in grade II disease. 24 patients (68.57%) from study group and 20 patients from control group (57.14%) had grade II disease. (24/35 in study group and 20/35 in control group), 8 patients (22.86%) from study group and 7 patients from control group (20.00%) had grade I disease. Grade III cancer was present in 3 patients (8.57%) of study group and 8 patients (22.86%) of control group.

6. Observations based on site of cancer of patients of oral cavity cancer :

Table 29 : Site-wise distribution of patients of oral cavity cancer

Site of cancer	Study Group	Control Group
Alvelous	2	1
Buccal Mucosa	11	11
Cheek	0	1
Epiglottis	0	2
Hypopharynx	1	0
Larynx	3	3
Lip	1	1
Mandible	1	0
Maxilla	0	1
Oropharynx	1	1
Post Cricoid	2	1
Pyriform Fossa	2	0
Retro molar Trigone	1	1
Supra glottis	0	1
Tongue	8	8
Vocal Cord	2	3
Total	**35**	**35**

Graph 6 : Number of patients according to site of oral cavity



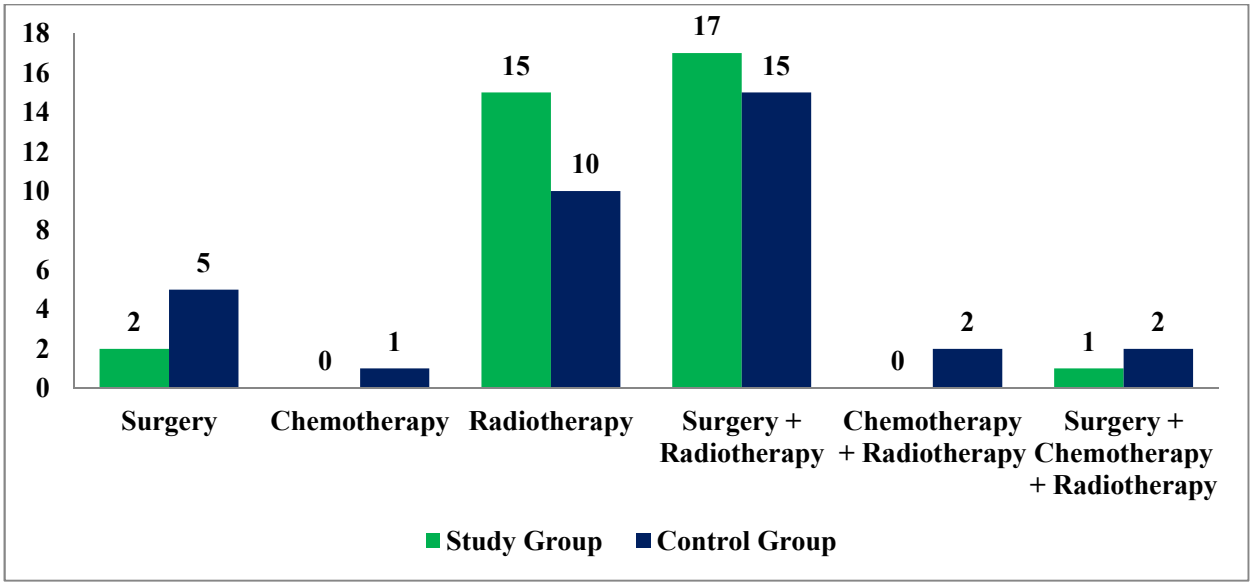
Maximum number of patients recruited in our study had cancer of buccal mucosa (11 patients in each group) and tongue cancer (8 patients in each group). 2 and 1 patient from study and control group had cancer of alveolus respectively, 1 patient from control group had cancer of cheek, maxilla and supraglottis; 3 patients from control group had cancer of epiglottis, 1 patient from study group had hypopharyngeal cancer, 3 patients from each group had laryngeal cancer. 1 patient from each group had cancers of lip, oropharynx and retromolar trigone. 1 patient suffered from mandibular cancer in study group. 2 patients from study group and 1 patient from control group had post cricoid cancer. 2 patients from study group suffered from cancer of pyriform fossa. 2 and 3 patients from study and control group respectively had vocal cord cancer.

7. Observations based on conventional treatment taken by patients of oral cavity cancer :

Table 30 : Distribution of patients of oral cavity cancer on basis of conventional treatment

Conventional treatment	Study Group	Control Group
Surgery	2	5
Chemotherapy	0	1
Radiotherapy	15	10
Surgery + Radiotherapy	17	15
Chemotherapy + Radiotherapy	0	2
Surgery + Chemotherapy + Radiotherapy	1	2
Total no. of patients	**35**	**35**

Graph 7 : Number of patients according to conventional treatment



Oral cavity cancer patients are treated with surgery, radiotherapy and chemotherapy according to stage of the disease. In our study 2 patients of study group and 5 patients of control group were treated with surgery alone, whereas 1 patient of control group was treated with chemotherapy alone. Total 25 patients from our study (15 from study group

and 10 from control group) were treated with radiotherapy alone. 17 patients from study group and 15 patients of control group were treated with a combination of surgery and radiotherapy. 2 patients from control group were treated with radiotherapy and chemotherapy, whereas 1 patient from study group and 2 patients from control group were treated with all 3 conventional treatment modalities. viz. surgery, radiotherapy and chemotherapy.

B. Clinical Data (mainly symptoms and Quality of Life) :
Intergroup Analysis (In-between Study and Control)

1. Karnofsky Score:

Karnofsky Performance Score (KPS) is used for measuring wellbeing and quality of life of cancer patients. Using this scale each patient is allocated a score on a linear scale between 0 (dead) and 100 (normally active, without evidence of disease), summarizing their ability to perform daily activities and the level of assistance they require in order to do so.

In our study, we measured Karnofsky score of study and control group patients at 3 time points viz,

a) Time point 'a' =
Before administration of Basti, Nasya, Mukhopakrama, Shirodhara and Karnapurana procedures in study group patients, similar time point of control group patients.

b) Time point 'b' =
For study group: at the end of Basti, Nasya, Mukhopakrama, Shirodhara and Karnapurana procedures i.e. 7^{th} day from time point a in control group patients.
For control group: 7^{th} day from time point 'a'.

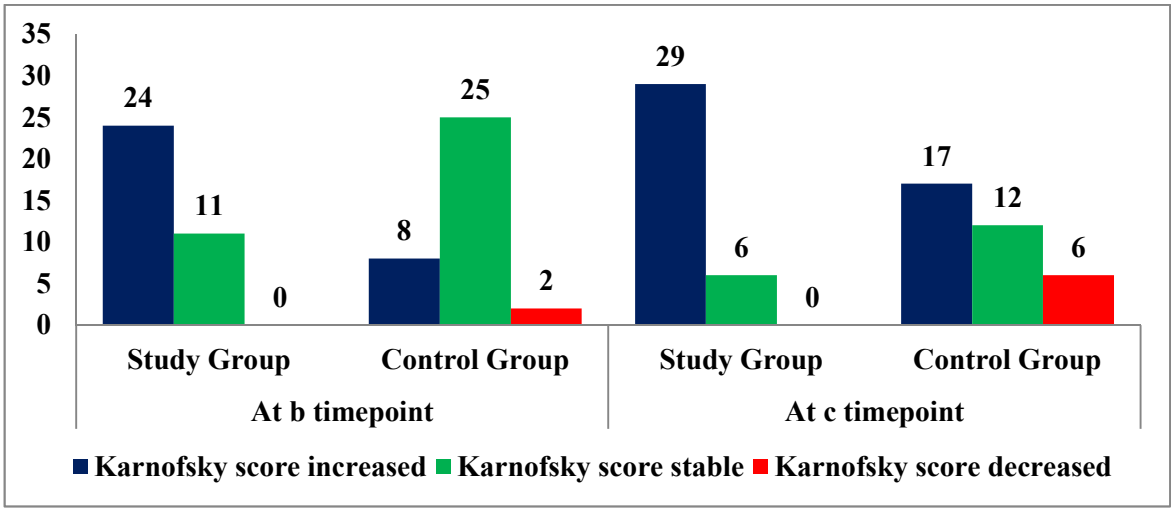
c) Time point 'c' =
For study group: one month after completion of Basti, Nasya, Mukhopakrama, Shirodhara and Karnapurana procedures.
For control group: one month after time point 'b'.

Treatment response was assessed on the basis of increase, stable and decrease of number of Karnofsky score at time point 'b' and 'c' as compared to time point 'a'.

Table 31 : Karnofsky score at time point 'b' and 'c'

Karnofsky score	At 'b' time point		At 'c' time point	
	Study Group	Control Group	Study Group	Control Group
Karnofsky score increased	24	8	29	17
Karnofsky score stable	11	25	6	12
Karnofsky score decreased	0	2	0	6

Graph 8 : Intergroup analysis by Karnofsky score



a. For time point 'b' -

It was observed that Karnofsky score had increased in 24 patients (68.57%) of study group and 8 patients (22.85%) of control group at time point 'b'.

The score remained stable in 11 patients (31.42%) of study group and 25 patients (71.42%) of control group.

At this time point, decrease in Karnofsky score was not seen in any patients of study group whereas it was seen in 2 patients (5.71%) of control group.

Overall improvement and maintenance of Karnofsky score was seen in all the 35 patients (100 %) of study group and 33 patients (94.28 %) of control group at time point 'b'.

b. For time point 'c' –

Similar observation about decrease in Karnofsky score was seen at time point 'c' in both study and control group.

It was observed that Karnofsky score had increased in 29 patients (82.85%) of study group and 17 patients (48.57%) of control group at time point 'c'.

The score remained stable in 06 patients (17.14 %) of study group and 12 patients (34.28%) of control group.

At this time point, decrease in Karnofsky score was not seen in any patients of study group whereas it was seen in 06 patients (17.14 %) of control group.

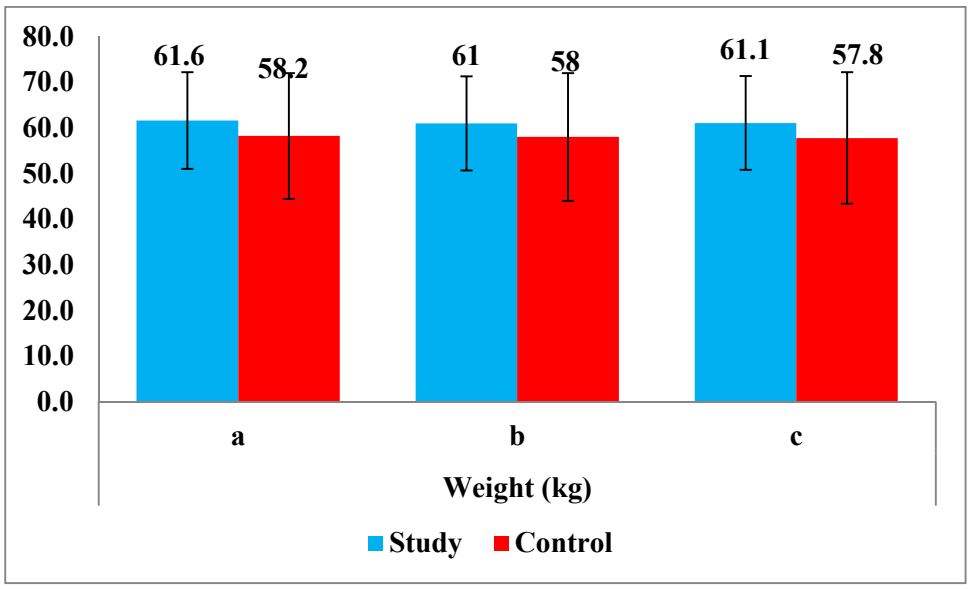
Overall improvement and maintenance of Karnofsky score was seen in all the 35 patients of study group and 29 patients (82.85%) of control group at time point 'c'.

2. Weight :

Table 32 : Comparative analysis of weight at time point 'a', 'b' and 'c'

	Weight		
	a	**b**	**c**
Study	61.6 ± 10.6	61 ± 10.3	61.1 ± 10.3
Control	58.2 ± 13.8	58 ± 14.0	57.8 ± 14.4
p values	---	--	--

Graph 9 : Intergroup analysis of weight



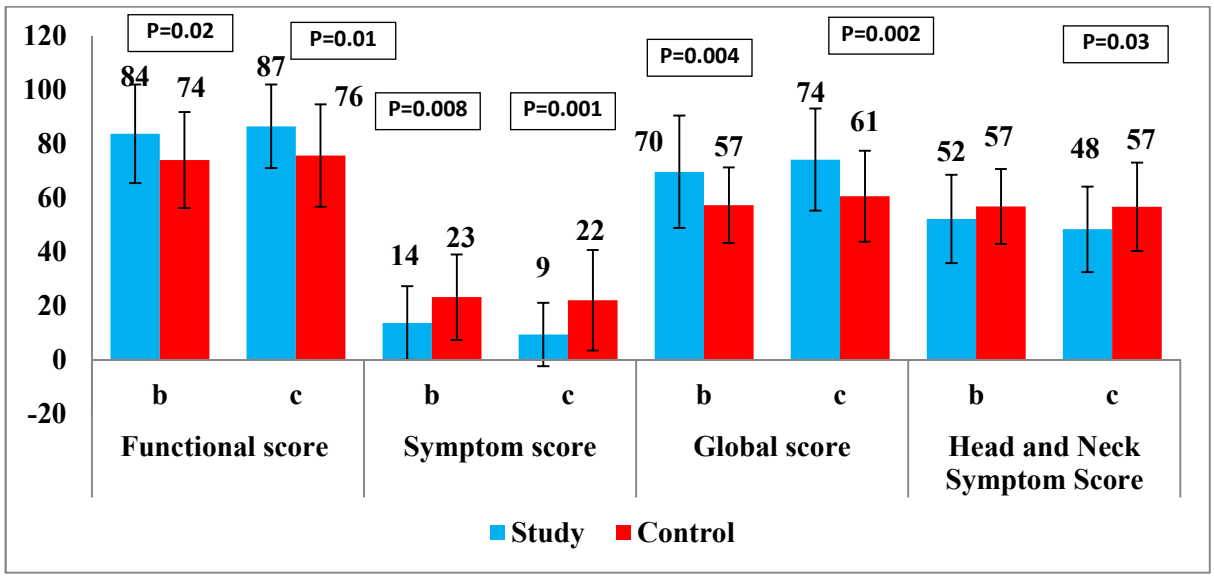
Weight remained almost constant at time points 'a', 'b' and 'c' in study and control groups respectively.

3. QLQ :

Table 33 : Comparative analysis grading of functional, symptomatic, global score and H&N 35 score at time point 'b' and time point 'c'

	Functional score		Symptom score		Global score		Head and Neck Symptom Score	
	b	c	b	c	b	c	b	c
Study	84±18.2	87± 15.5	14± 13.7	9± 11.8	70± 20.8	74± 18.9	52± 16.3	48± 15.9
Control	74± 17.8	76± 19.0	23± 15.9	22± 18.6	57± 14.0	61± 16.9	57± 13.9	57± 16.3
p values	0.02	0.01	0.008	0.001	0.004	0.002	----	0.03

Graph 10 : Analysis of functional score, symptoms score, global score and Head & Neck symptom score



QLQ C30 - A Quality of Life questionnaire derived from EORTC is used to assess the quality of life of all types of cancer patients.

It is categorized into three types of scores-

1) Functional score : Indicates day to day activities and functions.
2) Symptom score : Indicates severity of symptoms related to cancer.
3) Global score : Indicates overall well-being and Quality of Life.

In our present study, the mean functional score of study group patients at time point ‘b’ was 84 whereas that of the control group was 74 indicating significant result (p=0.02) in functional score of study group patients at the time point ‘b’.

Similarly significant result (p=0.01) was obtained for functional score at the time point ‘c’ in study group. At this time point, mean functional score of study group patients and control group patients was 87 and 76 respectively.

The mean symptom score of study group patients at time point ‘b’ was 14 whereas that of the control group was 23 indicating very significant result (p=0.008) in symptom score of study group patients at the time point ‘b’.

Similarly very significant result (p=0.001) was obtained for symptom score at the time point ‘c’ in study group. At this time point, mean symptom score of study group patients and control group patients was 09 and 22 respectively.

The mean global score of study group patients at time point ‘b’ was 70 whereas that of the control group was 57 indicating very significant result (p=0.004) in global score of study group patients at the time point ‘b’.

Similarly very significant result (p=0.002) was obtained for global score at the time point ‘c’ in study group. At this time point, mean global score of study group patients and control group patients was 74 and 61 respectively.

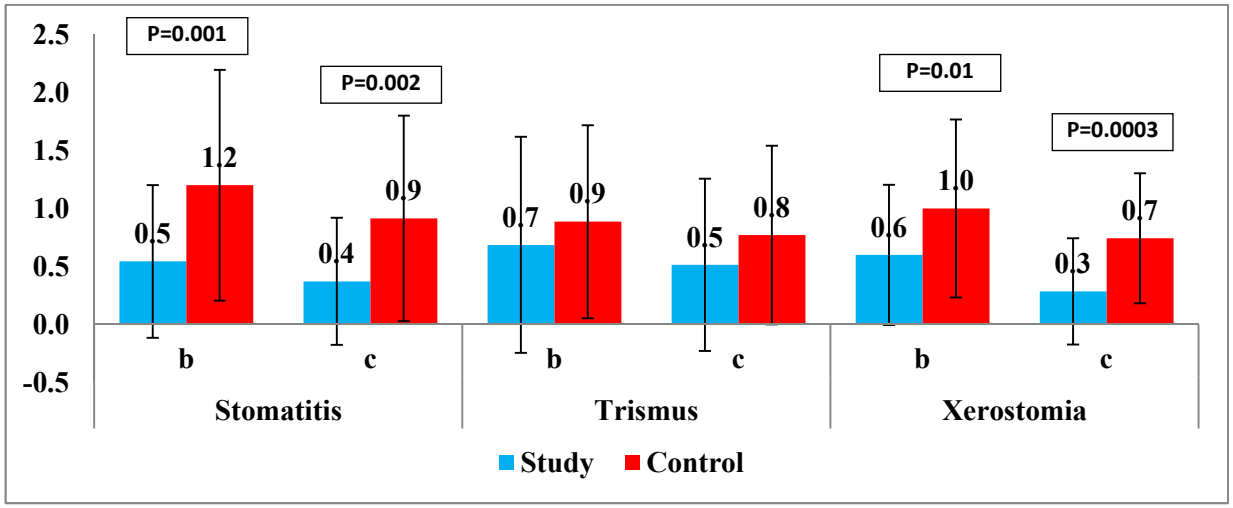
Regarding the Head and Neck (H&N 35) symptom score, at time point ‘b’, mean H&N symptom score was not significant in the study and the control group patients, whereas it was significant (p=0.03) at time point ‘c’ in study group. At this time point, mean H&N symptom score of the study group and control group patients was 48 and 57 respectively.

4. Analysis of symptoms of oral cavity cancers :

Table 34 : Comparative analysis of stomatitis, trismus and xerostomia at time point 'b' and time point 'c'

	Stomatitis		Trismus		Xerostomia	
	b	**c**	**b**	**c**	**b**	**c**
Study	0.5± 0.7	0.4± 0.5	0.7± 0.9	0.5± 0.7	0.6± 0.6	0.3± 0.5
Control	1.2± 1.0	0.9± 0.9	0.9± 0.8	0.8± 0.8	1.0± 0.8	0.7± 0.6
p values	0.001	0.002	--	--	0.01	0.0003

Graph 11 : Analysis of stomatitis, trismus, xerostomia



A) **Stomatitis :** It is a most common symptom seen in oral cavity cancer patients.

Very significant result (p=0.001) was obtained for this symptom at time point 'b'. In study group patients at time point 'b', mean grading of stomatitis was 0.5 whereas it was 1.2 in control group patients.

At time point 'c', mean grading of stomatitis in study group patients was 0.4, while in control group it was 0.9 indicating very significant result (p=0.002).

B) **Trismus :** It is also a symptom seen in oral cavity cancer patients.

In study group as well as control group patients at time point 'b' the mean grading of trismus was 0.7 and 0.9 respectively.

Also, at time point 'c', the mean grading of trismus in study group and control group patients was 0.5 and 0.8.

As per the graph, the mean gradation seen in this symptom at time point 'b' and 'c' was more but was of statistically non-significant value.

C) **Xerostomia :** It is one of the symptoms seen in oral cavity cancer patients.

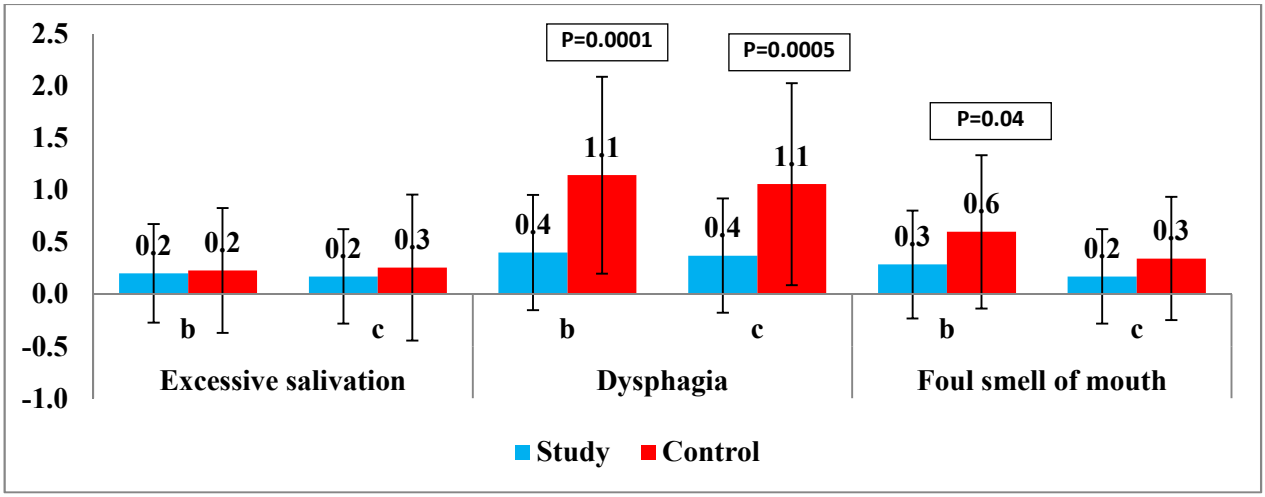
Significant result (p=0.01) was obtained for this symptom at time point 'b'. In study group patients at time point 'b', mean grading of xerostomia is 0.6 whereas it was 1.0 in control group patients.

At time point 'c', mean grading of xerostomia in study group patients was 0.3, while in control group it was 0.7 indicating extremely significant result (p=0.0003).

Table 35 : Comparative analysis of excessive salivation, dysphagia and foul smell of mouth at time point 'b' and 'time point 'c'

	Excessive salivation		**Dysphagia**		**Foul smell of mouth**	
	b	**c**	**b**	**c**	**b**	**c**
Study	0.2± 0.5	0.2± 0.5	0.4± 0.6	0.4± 0.5	0.3± 0.5	0.2± 0.5
Control	0.2± 0.6	0.3± 0.7	1.1± 0.9	1.1± 1.0	0.6± 0.7	0.3± 0.6
p values	---	---	0.0001	0.0005	0.04	---

Graph 12 : Analysis of excessive salivation, dysphagia and foul smell of mouth



D) **Excessive salivation :** It is one of the symptoms seen in oral cavity patients.
In study group as well as control group patients at time point 'b' the mean grading of excessive salivation was 0.2 and 0.2 respectively.
Also, at time point 'c', the mean grading of excessive salivation in study group and control group patients was 0.2 and 0.3.
The mean gradation seen in this symptom at time point 'b' and 'c' was statistically non-significant.

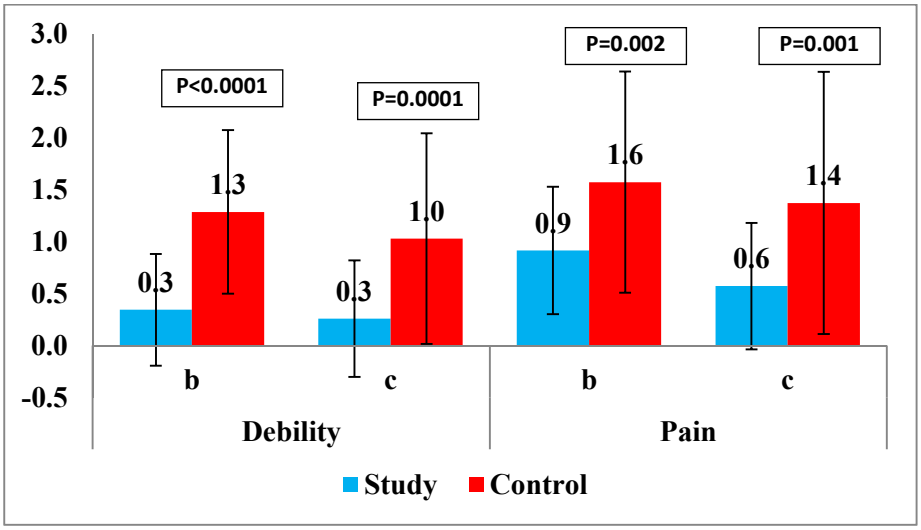
E) **Dysphagia :** It is one of the symptoms seen in oral cavity cancer patients.
Extremely significant result (p=0.0001) was obtained for this symptom at time point 'b'. In study group patients at time point 'b', mean grading of dysphagia was 0.4 whereas it was 1.1 in control group patients.
At time point 'c', mean grading of dysphagia in study group patients was 0.4, while in control group it was 1.1 indicating extremely significant result (p=0.0005).

F) **Foul smell of mouth :** It is also one of the common symptom seen in oral cavity cancer patients.
At time point 'b' significant result (p=0.004) was obtained for this symptom. In study group patients at time point 'b', mean grading of foul smell of mouth was 0.3 whereas it was 0.6 in control group patients.
At time point 'c', mean grading of foul smell of mouth in study group patients was 0.2, while in control group it was 0.3 indicating statistically non-significant.

Table 36 : Comparative analysis of debility and pain at time point 'b' and 'time point 'c'

	Debility		**Pain**	
	b	**c**	**b**	**c**
Study	0.3± 0.5	0.3± 0.6	0.9± 0.6	0.6± 0.6
Control	1.3± 0.8	1.0± 1.0	1.6± 1.1	1.4± 1.3
p values	< 0.0001	< 0.0001	0.002	0.001

Graph 13 : Analysis of debility and pain



G) **Debility :** It is one of the symptoms and also seen as a result of side effect due to conventional treatment in oral cavity cancer patients.

Extremely significant result ($p < 0.0001$) was obtained for this symptom at time point 'b'. In study group patients at time point 'b', mean grading of debility was 0.3 whereas it was 1.3 in control group patients.

At time point 'c', mean grading of debility in study group patients was 0.3, while in control group it was 1.0 indicating extremely significant result ($p=0.0001$).

H) **Pain :** It is also one of the most common associated symptoms in patients of oral cavity cancer.

At time point 'b' very significant result ($p=0.002$) was obtained for this symptom. In study group patients at time point 'b', mean grading of pain was 0.9 whereas it was 1.6 in control group patients.

At time point 'c', mean grading of pain in study group patients was 0.6, while in control group it was 0.5 indicating statistically very significant.

Intragroup Analysis : (Time point 'b' to 'a')

Table 37 : Intragroup Analysis at time point 'b' to 'a'

Sr. No	Parameters	Study Group				Control Group			
		Mean - a	Mean - b	p value	Significance	Mean - a	Mean - b	p value	Significance
1	**Karnofsky score**	80.9	88.0	<0.0001	Extremely Significant	74.3	75.7	0.0960	
2	**Weight**	61.6	61.0	0.0006	Extremely Significant	58.2	58.0	0.0463	Significant
3	**Functional score**	78.3	83.9	0.0003	Extremely Significant	72.7	74.1	0.4989	
4	**Symptom score**	17.8	13.7	0.0020	Very Significant	27.3	23.3	0.0437	Significant
5	**Global score**	63.3	69.8	0.0002	Extremely Significant	57.2	57.4	0.9501	
6	**QLQ H&N35**	57.4	52.3	0.0003	Extremely Significant	59.5	56.9	<0.0001	Extremely Significant
7	**Stomatitis**	1.3	0.5	<0.0001	Extremely Significant	1.3	1.2	0.1032	
8	**Trismus**	1.0	0.7	0.0002	Extremely Significant	1.0	0.9	0.0831	
9	**Xerostomia**	0.9	0.6	0.0004	Extremely Significant	1.1	1.0	0.1603	
10	**Excessive salivation**	0.4	0.2	0.0062	Very Significant	0.3	0.2	0.0831	
11	**Dysphagia**	0.7	0.4	0.0002	Extremely Significant	1.2	1.1	0.3244	
12	**Foul smell of mouth**	0.7	0.3	<0.0001	Extremely Significant	0.7	0.6	0.1603	
13	**Debility**	0.7	0.3	<0.0001	Extremely Significant	1.4	1.3	0.0437	Significant
14	**Pain**	1.6	0.9	<0.0001	Extremely Significant	1.7	1.6	0.1835	

Intra group analysis of patients at time point 'b' with respect to time point 'a' showed significant results in all the 14 parameters mentioned in the above table in study group patients.

In control group, significant results were found in 4 of the 14 parameters viz. weight, symptom score of QLQ C-30, QLQ H&N 35 and debility in oral cavity cancer patients.

Intragroup Analysis : (Time point 'c' to 'a')

Table 38 : Intragroup Analysis at time point 'c' to 'a'

Sr. No.	Parameters	Study Group				Control Group			
		Mean - a	Mean - c	p value	Significance	Mean - a	Mean - c	p value	Significance
1	Karnofsky score	80.9	90.0	<0.0001	Extremely Significant	74.3	76.9	0.0712	
2	Weight	61.6	61.1	0.0145	Significant	58.2	57.8	0.1006	
3	Functional score	78.3	86.6	<0.0001	Extremely Significant	72.7	75.7	0.1908	
4	Symptom score	17.8	9.5	0.0001	Extremely Significant	27.3	22.1	0.0462	Significant
5	Global score	63.3	74.3	<0.0001	Extremely Significant	57.2	60.7	0.1690	
6	QLQ H&N35	57.4	48.5	<0.0001	Extremely Significant	59.5	56.8	0.0034	Very Significant
7	Stomatitis	1.3	0.4	<0.0001	Extremely Significant	1.3	0.9	0.0001	Extremely Significant
8	Trismus	1.0	0.5	<0.0001	Extremely Significant	1.0	0.8	0.0062	Very Significant
9	Xerostomia	0.9	0.3	<0.0001	Extremely Significant	1.1	0.7	0.0004	Extremely Significant
10	Excessive salivation	0.4	0.2	0.0032	Very Significant	0.3	0.3	0.4875	
11	Dysphagia	0.7	0.4	0.0003	Extremely Significant	1.2	1.1	0.0576	
12	Foul smell of mouth	0.7	0.2	<0.0001	Extremely Significant	0.7	0.3	0.0004	Extremely Significant
13	Debility	0.7	0.3	<0.0001	Extremely Significant	1.4	1.0	0.0031	Very Significant
14	Pain	1.6	0.6	<0.0001	Extremely Significant	1.7	1.4	0.0102	Significant

Intra group analysis of patients at time point 'c' with respect to time point 'a' showed significant results in all the 14 parameters mentioned in the above table in study group patients.

In control group, significant results were found in 8 of the 14 parameters viz. symptom score of QLQ C-30, QLQ H&N 35, stomatitis, trismus, xerostomia, foul smell of mouth, debility and pain in oral cavity cancer patients.

The above observations proved the efficacy of the treatment protocol of Basti, Nasya, Mukhopakrama, Shirodhara and Karnapurana procedures in study group at time point ‘b’ and ‘c’ indicating long lasting efficacy of this treatment protocol in patients of oral cavity cancers.

DISCUSSION

The discussion is made on the basis of following points :

1. **Oral cavity cancers** : Symptoms and treatment from Ayurvedic perspective.

2. **Demographic data** : Based on the age-wise, sex-wise, socio-economic status wise, stage-wise, grade-wise, conventional treatment taken and site-wise distribution of the oral cavity cancer patients.

3. **Observations and Results** : In this part, assessment is done by two methods –

a. **Inter group analysis** : The analysis is done between two different groups at a specific time point. In this study, analysis is done at time point 'b' and time point 'c' between the study and group.

b. **Intra group analysis** : The analysis is done in same group at two different time points with respect to a particular time point. In this study, analysis is done between time point 'b' and time point 'c' with respect to time point 'a' in study group as well as control group.

Discussion is made on parameters like Karnofsky score, QLQ C-30 and QLQ H&N 35, weight, symptoms of oral cavity cancer patients viz. stomatitis, trismus, xerostomia, excessive salivation, dysphagia, foul smell from mouth, debility and pain in the intergroup and intragroup.

Intergroup assessment is useful to compare results in patients of two different groups. Intragroup assessment is useful in comparing the benefits of a specific treatment modality in patients of the same group at specific time points.

1. Discussion on oral cavity cancers, their symptoms and treatment from Ayurvedic perspective

Oral cavity cancers rank among first 3 cancers in India. It is more common in males than females due to more incidence of addiction like tobacco, cigarette, and alcohol consumption in males.

Oral cavity cancers mainly include cancers of lip, tongue, buccal mucosa, alveolus, cheek, maxilla, mandible, post cricoid, pyriform fossa, retromolar trigone, palate, vocal cord, oropharynx, hypopharynx and larynx.

Sushrutacharya described total sixty five Mukharoga (diseases of oral cavity) occurring at seven different sites of oral cavity, namely at Ostha (lips), Dantamula (gums), Danta (teeth), Jivha (tongue), Talu (palate), Gala (throat) and Galadi (entire oral cavity).

Among sixty five Mukharoga, almost thirteen Mukharoga show similarity with signs and symptoms of oral cavity cancers and symptoms of adverse effects of radiotherapy, which is a treatment of choice in oral cavity cancer. Commonly seen signs and symptoms of oral cavity cancers are presence of tumors, ulcerative lesions, stomatitis, trismus, sticky salivation, foul smell in mouth, loss of taste, anorexia, dysphagia, debility, weight loss, whereas adverse effects of radiotherapy and chemotherapy in oral cavity cancer are stomatitis, xerostomia, trismus, loss of taste, excessive and stick salivation, nausea, dysphagia, fever, debility and weight loss. Inflammation and infection in oral cavity is also common due to poor hygiene of oral cavity.

Among all types of cancers, aggressively hampered quality of life is evident in oral cavity cancer patients due to poor oral intake food. In this scenario, oral cavity cancer patients should be managed by curative treatment for cancer and palliative treatment of symptoms of disease or adverse effects of conventional treatment.

Kaphaja Jivha Kantaka, Kapha dominant sharp elevation of taste buds is a type of Jivha Vikara (disease of tongue) and can be treated with Gandusha (gargling) with decoction of Kaphaghna herbs namely Triphala, Haridra (*Curcuma longa*), Khadira (*Acacia catechu*), Nimba (*Azadiracta indica*).

Talu Arbuda is a red colored tumor at palate and is caused due to vitiation of three Doshas and Rakta Dhatu. It has a tendency of recurrence even after excision and thus difficult to treat.

Galagraha is a tumor in oropharynx causing dysphagia and is usually associated with Jwara (fever), Arati (malaise) and Mukhasrava (excessive salivation). This disease is caused due to vitiation of Kapha dominant three Doshas and can be managed with Gandusha (gargling) to some extent.

Galarbuda is a tumor in throat / oropharynx, which is Tridosha dominant. The line of treatment described in this disease is Snehana (Abhyanga), Nasya, Gandusha (gargling) and Pratisarana (local application of ghee or oil).

Pitta Dosha dominant Tridoshaja Mukharoga called as Sarvasara Mukharoga resembles stomatitis. It's main characteristic is inflammation and ulcer. Gandusha (gargling) of Pitta pacifying medicines like Yastimadhu, Nimba, milk and Nasya are recommended in this condition.

Kapharbuda is a Kapha Dosha dominant Tridoshaja tumor at buccal mucosa, which can be treated with Mukha Pratisarana (local application of herbal paste or medicated ghee or oil).

A condition similar to halitosis, called as Putimukha is caused due to vitiation of three Doshas and Rakta Dhatu. The treatment of choice for Putimukha is Tikshna Nasya.

Talushosha, dryness of mouth is a consequence of Vata-Pitta dominant Tridosha Dushti. Xerostomia is commonly seen in oral cavity cancer patients as a major side effect of radiotherapy. Gandusha with Snigdha Dravya and Nasya are recommended in this condition.

Talupaka (ulceration of palate) is a Pitta dominant Tridoshaja condition, which can be treated with Pittaghna Gandusha and Pratisarana.

A progressive swelling / abscess underneath tongue causing immobilization of tongue, which is caused due to vitiation of Kapha dominant Tridosha and Rakta Dhatu is called as Alasa. The line of treatment for Alasa is Gandusha (Gargling).

Danta Vidradhi, which is an abscess at gums or alveolar region, has a dominance of Tridosha and Rakta Dhatu. The treatment described for this disease is Gandusha (Gargling) with Triphala and Nimba and Nasya of Yashtimadhu Ghruta.

Raktarbuda at lip region, a disease caused due to vitiation of Tridosha and Rakta Dhatu is difficult to treat and has a characteristic swelling at lip region.

Hanugraha, a condition similar to trismus / lock jaw is caused due to vitiation of Vata dominant Tridosha and has to be treated with Snigdha Chikitsa.

Considering the anatomy and physiology of organs involved in oral cavity, following Samprapti Ghatak (factors / elements / organs) should be taken care of while treating diseases of oral cavity including cancer.

1. Vitiation of Kapha Dosha:

क्रुध्दाः श्लेष्मोल्बणादोषाः कुर्वन्तेअंतर्मुखेगदान् ।

वा.उ. २१/३

Mukha, oral cavity is a site of Bodhaka Kapha, which is mainly responsible for keeping oral cavity moist, proper recognition of taste of food, easy assimilation and swallowing of food. Vitiation of Bodhaka Kapha is responsible for various diseases of oral cavity and hampers functions of various organs of oral cavity.

2. Rakta Dhatu Pradhosha / Dushti:

Jivha (tongue) is described in Sushruta Samhita as originated from Kapha Dosha and Rakta Dhatu.

कफशोणितमांसानांसारात् जिव्हा प्रजायते ।

सु. शा. ४/२८

Thus proper functioning and normal status of Rakta Dhatu is essential to maintain health of oral cavity. Vitiation of Rakta Dhatu is therefore responsible for various diseases of oral cavity.

Pitta and Rakta dominant symptoms like inflammation, stomatitis, ulcers, burning sensation, bleeding are usually seen in various diseases of oral cavity including cancer.

3. Mansa Dhatu Pradosha:

Organs of oral cavity like tongue, lips, cheeks, tonsils are formed by Mansa Dhatu. Thus Mansapradoshaja Vikara like Granthi, Arbuda, commonly occurs at oral cavity, which are treated as oral cavity cancers.

4. Shotha / Vranashotha and their various types

Acharya Charaka has clearly mentioned in Trishothiya Adhyaya that Granti, Arbuda are various forms of Shotha (inflammation) and occur at various sites in the body. Sushrutacharya has also quoted that Granthi, Arbuda, Visarpa are the endpoint of untreated Dushtavrana and Vranashotha. Thus management of Shotha / Vranashotha has to be taken into account while treating Dushta Granthi / Dushta Arbuda (malignant lesions).

A concept of Dushta Vrana is elaborately described in Sushrut Samhita along with its causative factors, signs-symptoms and treatment. As Dushta Vranashotha, Dushta Granthi, Dushta Arbuda, Dushta Nadivrana, Dushta Visarpa are the manifestations of advanced stages of Dushta Vrana, these disease should be treated with similar treatment principles of that of Dushta Vrana.

Shotha, Vranashotha and Dushta Vrana are caused by vitiation of Tridosha (Vata, Pitta and Kapha). They are categorized as per dominance of Dosha. Vata dominant Shotha is

very painful, Pitta dominant Shotha shows signs of inflammation like hot in touch, burning sensation, red colored, whereas Kapha dominant Shotha has profuse secretions especially pus formation.

5. Dhatugata and Dhatupaka Awastha:

Concept of Dhatugata Awastha is described in consistent with diseases Jwara (fever), Kushtha (skin diseases), Vata Vyadhi (diseases of nervous system) and Masurika (measles) in Ayurvedic text, but it is also applicable to other diseases including cancer. The concept states invasion and manifestation of particular disease in successive Dhatus (deeper and deeper tissues) namely Rasa, Rakta, Mansa, Meda, Asthi, Majja and Shukra as disease progresses. In case of cancer, metastasis in local and distant organs is similar to Dhatugata Awastha. In case of oral cavity cancers, metastasis in lymph nodes and in neck region, even up to the level IV and metastasis in lungs are common and are considered as Dhatugata Awastha.

Dhatupaka Awastha is an advanced neurotic stage of Vranashotha. The signs and symptoms of Mansa Dhatupaka are mentioned in Ayurvedic text.

मांसदोषेण जानीयात् अर्बुदंमांससंभवम् ।
शीर्यन्ते यस्य मांसानि यत्र सर्वाः च वेदना ।।
विद्यात् तं मांसपाकं तु सर्वदोषकृतं भिषक् ।

सु. नि. १४ । १४

This stage is characteristic of complete destruction of organ and is incurable. Locally advanced oral cavity cancers, invaded in nearby tissues, muscles, bones and lymphnodes can be termed as Dhatupaka Awastha.

6. Dhatwagni Dusthi :

Jatharagni and Dhatwagni play an important role in maintaining proper functions of Dhatus, organs and system. Agni Vruddhi and Agni Mandya are abnormal states of Agni, where Agni Vruddhi, leads to Dhatu Kshaya, whereas Agni Mandya leads to Dhatu Vruddhi and Aama Nirmiti. Dhatwagnimandya is responsible for abnormal growth in all

types of cancer. Thus normalization of Dhatwagni with the help of Shamana Chikitsa (Deepana – Pachana) and Panchakarma is a treatment of choice in cancers.

Treatment principles of oral cavity cancers from Ayurvedic perspective considering Samprapti Ghatak :

1. **Treatment of Mansa Pradoshaja Vyadhi:**
   Mansa Pradoshaja Vikara should be treated with Shastra Karma (Surgery), Kshara Karma (medicine which possess scraping / Lekhana action) and Agni Karma (type of cauterization). Surgery is the first line treatment of cancers of oral cavity, followed by Kshara Chikitsa.

2. **Treatment of Vrana i.e. Shashti Upakrama** :
   Sushrutacharya described 60 treatment modalities for management of Vrana and its various forms like Dushta Granthi, Dushta Arbuda. These treatment modalities are a combination of systemic treatment like Panchakarma and local management of Vrana like Gandusha, Pratisarana, Lepa.

3. **Treatment modalities described in Mukharoga**:
   Vitiated Kapha Dosha is a leading cause of diseases of oral cavity. Therefore, treatment of Kapha Dosha like Gandusha with Kaphaghna herbs, Nasya with Kapha-nashaka oils is recommended in diseases of oral cavity for management of symptoms like stomatitis, excessive salivation, foul smell of mouth, loss of taste, etc.

4. **Preventive Aspect :**
   While describing the etiological factors for development of Mukha Roga, Acharya Vaghbhat has mentioned improper brushing habits, not following procedures like Dhoomapana (inhaling medicated fumes), Vamana (emesis), Gandusha (gargling with medicated decoctions) and Raktamokshana (blood-letting) whenever required can also lead to diseases of oral cavity. Therefore incorporating procedures like Danta Dhawana, Nasya, Gandusha, Karnapurana, Abhyanga as recommended in Dincharya and following it properly can be helpful in improving Quality of Life and preventing from such a dreadful disease.

DISCUSSION ON RESULTS

1. **Discussion on age:**

   Worldwide statistics shows that oral cavity cancers most often occur in people over the age of 40 years. Similar observations are seen in our study. 54/70 patients in present study are above the age of 40 years.

2. **Discussion on sex:**

   Worldwide statistics shows that oral cavity cancers most often occur in males than females. Similar observations are seen in our study. 50/70 patients in present study are males.

3. **Discussion on socio-economic status:**

   Society comprises of various socio-economic strata having their distinct life-styles. These directly or indirectly have an impact on their risk factors for oral cavity cancers. Due to advancement in science and technology on a global scenario, newly emerging job opportunities with better monetary benefits, standard of living has improved which has changed the financial potential of the middle socio-economic strata as compared to the earlier decades. There is a sudden splurge seen in this stratum on various kinds of addictions due to newly emerging trends like lounges, hookah parlors, etc. Also, online availability of various forms of tobacco and alcohol has made it easier to acquire for the consumers. Cumulatively it is seen that the present incidence of oral cavity cancer seen in middle socio-economic strata and low socio-economic strata is almost similar.

   The low socio-economic strata in India is affected mostly due to lack of education and awareness, a wide exposure to risk factors such as tobacco chewing, gutkha, betel quid, bidis, cigarettes, etc. There is also lack of personal and oral hygiene seen in this stratum.

   Similar observations are seen in our study where 39 out of 70 patients are from middle socio-economic class and 30 out of 70 patients are from low socio-economic class

4. Discussion on stage:

AJCC Cancer Staging manual was used confirm stage of oral cavity cancer in our study. Staging is done on the basis of 3 characters – 1) T = size of tumor, 2) N = nodal involvement and 3) M = metastasis of cancer. Based on these 3 characters, staging is done from stage 0 to IV.

Oral cavity cancers are common in low socio-economic group, which has lack of medical education in India. Thus most of the patients are diagnosed in last stage of disease i.e. Stage III & IV disease. In our study 23/35 patients from study group and 23/35 patients from control group have stage III and IV disease.

5. Discussion on grade:

Grade of cancer is predictor of outcome of disease. Low grade cancers spread slowly and have better survival, whereas high grade cancers spread fast and have bad prognosis. In our study maximum number of patients have grade II cancer.

6. Discussion on site of cancer:

Distribution of types of cancer is almost equal in both study and control group.
Among oral cavity cancers, buccal mucosa and tongue cancers are common cancers. Our study also showed similar findings.

7. Discussion on conventional treatment:

A choice of treatment for oral cavity cancer patients is surgery and radiotherapy. Stage IV patients are generally treated with additional concurrent or curative radiotherapy. Maximum number of patients from our study are treated with radiotherapy alone (25/70) and with a combination of surgery and radiotherapy (32/70).

8. Discussion on effect of treatment on Karnofsky score, weight, QLQ C-30 and QLQ H&N 35 and symptoms of Mukharoga.

a. Karnofsky Score :

Karnofsky score is used to assess well-being of patient. It is recorded by the physician to assess treatment response. 0 to 100 scale is used for measuring Karnofsky score, where '0' means fatal condition, whereas '100' indicate healthy status. Panchakarma procedures like Basti, Nasya along with Snehana (Abhyanga), Swedana help to relax body, improve appetite, digestion and sleep and therefore to improve well-being of patients. Extremely significant results are found for Karnofsky score in study group patients at time point 'b' ($p < 0.0001$) and 'c' ($p < 0.0001$) when compared with 'a', in intragroup assessment.

b. Weight :

Weight is a measure of proper nourishment, which is hampered in oral cavity cancer patients due to disease itself or due to adverse effect of radiotherapy and chemotherapy. In our study, extremely significant and significant results are found in terms of weight gain at time point 'b' ($p = 0.0006$) and 'c' ($p = 0.0145$) when compared with time point 'a', during intragroup analysis in study group.

Snehana (Abhyanga) and Matra Basti are known treatment modalities for increasing strength and gaining weight. Bala Taila used for Snehana is also beneficial for increasing strength.

c. QLQ C 30 and H&N 35 :

QLQC30 (version 3) of EORTC is a questionnaire of 30 questions to measure Quality of Life (QoL) of cancer patients from their own perspectives. It is common for all types of cancers. Question number 1 to 28 are answered in 4 options, namely, 1 =not at all; 2=a little; 3=quite a bit; 4=very much. Question numbers 29 and 30 are to be answered from 1 to 7 scales in which 1 denotes very poor whereas 7 denotes excellent.

QLQ C30 consists of functional, symptom and global scores.

Daily activities / functions of patients are measured by functional score which is calculated using questions 1 to 7 and 20 to 27.

A raw mean function score is converted into final functional score using an equation,

$$\frac{1-(Mean\ Raw\ Score)}{\text{Range}} \times 100$$

High functional score represents high /healthy level of functioning.

Symptom score, which is indicative of symptomatology is calculated using question numbers 8 to 19 and 28. Final symptom score is calculated using an equation,

$$\frac{(\ Raw\ Score-1)\ \}}{\text{Range}} \times 100$$

High symptom score represent high level of symptomatology.

Global score indicates assessment of overall health and quality of life from patient's own perspectives which is assessed by question numbers 29 and 30. Final global score is calculated by using equation,

$$\frac{(\ Raw\ Score-11)}{\text{Range}} \times 100$$

High global score indicates healthy status and represent high quality of life.

In our study, in the inter group analysis, functional, symptom and global score are calculated at time points 'b' and 'c' and compared in study and control groups. Functional score at time point 'b' (p=0.02) and time point 'c' (p=0.01) is significant in study group. Symptom score is very significant at time point 'b' (p=0.008) and time point 'c' (p=0.001) in study group. Global score is very significant at time point 'b' (p=0.004) and time point 'c' (p=0.002) in study group. Head and Neck (H&N 35) symptom score is significant (p=0.03) at time point 'c' in study group. Panchakarma procedures like Basti, Nasya along with Snehana (Massage), Swedana, Gandusha, Mukha Pratisarana, Shirodhara and Karnapurana helps to pacify the Vata Dosha along-with Pitta and Kapha Dosha.

Snehana with Bala Taila along with Swedana with decoction of Dashmoola helps to pacify Vata Dosha and is also effective for stiff and immobilized joints.

Dashamoola oil used in Matra Basti acts as Bruhana and also helps in detoxification resulting in improvement of Agni and Bala. Gandusha, Mukha Pratisarana, Nasya and

Karnapurana helps in reducing the pain and other symptoms like stomatitis, xerostomia, trismus, dysphagia, etc and hence there is improvement in symptom score. Shirodhara with Jatamansi oil is effective in debility. The overall effect of the treatment regimen of study group resulted in betterment in day to day activities and functions of the patients along with significant relief in the symptoms and side effects from conventional treatment of oral cavity cancer. Thus there is an improvement in the well-being and Quality of Life in these patients.

Difference of each score between time points 'b' and 'a' and time points 'c' and 'a' are also calculated and significance is recorded in intragroup analysis. In this analysis functional score ($p=0.0003$) and global score ($p=0.0002$) are extremely significant at time point 'b' where as symptom score is very significant (0.002) in study group. However, in control group only symptom score is found to be significant (0.0437). Head and Neck (H&N 35) symptom score is extremely significant at time point 'c' in study group ($p=0.0003$) and control group ($p<0.0001$). At time point 'c', functional score ($p<0.0001$), symptom score ($p=0.0001$) and global score ($p<0.0001$) are extremely significant in study group. However, in control group only symptom score is found to be significant ($p=0.0462$). Head and Neck (H&N 35) symptom score is extremely significant at time point 'c' in study group ($p<0.0001$) and very significant in control group ($p<0.0034$). The treatment protocol showed remarkable improvement in the patients of study group at time point 'b' as well as 'c' which indicates long lasting efficacy of treatment protocol.

d. Stomatitis :

Stomatitis is caused due to vitiation of Pitta Dosha and Rakta Dhatu. It resembles Sarvasara and Talupaka diseases mentioned in Mukharoga in Sushrut Samhita. Stomatitis is a presenting symptom of oral cavity cancers as well it is often seen as a side effect of radiotherapy. In inter group assessment, very significant result of Matra Basti, Nasya, Gandusha, Mukha Pratisarana, Shirodhara and Karnapurana are obtained in study group at time point 'b' ($p = 0.001$) and 'c' ($p = 0.002$). In intragroup assessment, extremely significant results are obtained in study group at time point 'b' and 'c' ($p<0.0001$), however similar results are obtained in control group only at time point 'c' ($p=0.0001$).

Stomatitis in oral cavity cancer is a local expression generalized (Sarvadehik) Pitta Vruddhi in body. Thus local as well as a generalized Pitta pacifying treatment is beneficial in stomatitis. Snehana i.e. Abhyanga with Bala Taila is useful in pacifying Pitta Dosha due to its Pitta pacifying ingredients Bala (*Sida cordifolia*), Chandan (*Santalum alba*), Shaileyaka (*Parmelia perlata*), Shatavari (*Asparagus racemosus*) and Punarnava (*Boerrhavia diffusa)*. Many times stomatitis is associated with constipation. Matra Basti with Dashamoola Taila help to eliminate accumulated toxins and fecal matter from intestines and rectum and relieves constipation by the mechanism of Anulomana. In this manner Matra Basti is beneficial to treat stomatitis. Nasya is a treatment of choice of head and neck diseases. Yashtimadhu oil used for Nasya has Pitta pacifying effect and therefore beneficial in stomatitis. Gandusha is also recommended for Mukha Roga (diseases of oral cavity). Triphala and Harida used in Gandusha possess Raktaprasadana and Ropana action and thus useful in management of stomatitis. Mukhapratisarana with Yashtimadhu Ghruta is highly effective in stomatitis, as Yashtimadhu and ghee both possess wound healing (Ropana) and Pitta pacifying properties.

e. Trismus :

Trismus is Vata Kapha dominant Tridoshaja disease. In Ayurvedic text it is described as "Hanugraha," a kind of Mukharoga. Trismus is characterized by inability to open mouth. In oral cavity cancers, trismus is seen either due to tumor nearby temporo-mandibular joint or as an adverse effect of radiotherapy. Various types of 'Snigdha Chikitsa'is advised in Hanugraha in Ayurvedic texts.

In our study, during intra group analysis, extremely significant results are obtained for Hanugraha in study group at both time-points i.e at time-point 'b' ($p=0.0002$) and at time-point 'c' ($p<0.0001$). These results are seen due to administration of various forms of Snigdha Chikitsa in the form of Snehana (Abhyanga), Matra Basti, Nasya, Mukhapratisarana, Shirodhara and Karnapurana, Snehana with Bala Taila was additionally beneficial to pacify Vata Dosha and softening of muscles of oral cavity. Swedana followed by Snehana is effective for mobilization of immobilized joints.

सन्धिन्स्तब्धान् चेष्टयेत् आशुयुक्ता ।

Therefore Swedana is effective in reducing trismus. Dashamoola decoction used for Swedana, additionally pacifies Vata and Kapha Dosha. Dashamoola oil used in Matra Basti and Karnapurana is effective in pacifying Vata and Kapha Dosha, which are important factors in pathogenesis of Trismus. Yashtimadhu oil used for the treatment of Nasya pacifies Kapha and Vata Dosha. Nasya itself helps to relieve trismus by strengthening muscles and joints of oral cavity and by pacifying Vata Dosha, as described in Ayurvedic texts.

Gandusha and Mukha Pratisarana are the treatment of choice of Mukha Vyadhi. Triphala and Haridra used for preparing decoction of gargling are beneficial to treat Shotha (inflammation) inside oral cavity caused due to tumor or as a side effect of radiotherapy. It also helps to treat secondary fungal and bacterial infections and thus effective in trismus. Yashtimadhu Ghruta treats inflammation by applying it in oral cavity and successively reduces trismus.

f. Xerostomia :

Xerostomia means dryness of mouth, which usually occurs as an adverse effect of radiotherapy in head and neck cancers. It is Vata-Pitta dominant Tridoshaja disease and called Talushosha in Ayurveda. Gandusha and Nasya are the treatment modalities recommended for Talushosha. Significant results are obtained for xerostomia at time point ‘b’ ($p = 0.01$), which extremely significant results obtained at time point ‘c’ ($p= 0.0003$) in study group. During intragroup assessment, extremely significant results are found in study group at time point ‘b’ ($p = 0.0004$) and time point ‘c’ ($p<0.0001$), while similar results are obtained only at time point ‘c’ ($p=0.0004$) in control group.

Study group patients in our clinical trial got significant relief in xerostomia with Basti Chikitsa using Dashamoola oil, Nasya with Yashtimadhu oil, Snehana (Abhyanga) with Bala Taila, Mukhapratisarana with Yashtimadhu Ghruta and Karnapurana with Dashamool Taila. All these procedures and medicines used for the procedures pacify Vata and Pitta Dosha and import Snigdha Guna in body.

g. Excessive Salivation :

Excessive salivation is a symptom of Kapha dominant Mukharoga. Additionally in oral cavity cancers this symptom is seen as a side effect of radiotherapy. It is termed as

Mukhasrava in Sushrut Samhita and described as an associated symptom of a disease, Galagraha. In our study, in intra group analysis, very significant results are obtained in study group patients at time points 'b' (p= 0.006) and 'c' (p=0.0032) when compared with time point 'a'. Gandusha with Kapha-nashaka medicines is a treatment of choice in excessive salivation. Significant results in this symptom in study group patients are mainly attributed to Kaphaghna Gandusha with Triphala and Haridra decoction. Nasya with Yashtimadhu oil and Swedana with Dashamoola decoction imparted additional benefit of pacifying Kapha Dosha in this symptom.

h. Dysphagia :

Dysphagia meaning difficulty in swallowing is commonly seen in oral cavity cancer patients due to tumor itself or due to side effect of radiotherapy. It can happen due to obstruction of tumor or inflammation in oral cavity or dryness of mouth or trismus or due to secondary infections.

Gandusha and Mukha Pratisarana are important treatment modalities to treat dysphagia. In this study Gandusha with decoction of Triphala and Haridra and Mukhapratisarana of Yashtimadhu Ghruta were administered to study group patients, which possess characteristic anti-inflammatory, anti-microbial, anti-fungal and anti-tumor activity. Mukhapratisarana is also beneficial to reduce dryness of mouth and trismus.

As per Ayurvedic principles, dysphagia occurs mainly due to Vimargagamana (change in normal direction) of Prana and Udana Vayu. This condition can be best treated with Vatanulomana. Therefore a course of Matra Basti is effective in management of dysphagia.

Extremely significant results are obtained for dysphagia in study group at both time points during intergroup assessment, at time point 'b' (p = 0.0001) and time point 'c' (p=0.0005). Moreover, similar results were seen in study group at time point 'b' (p = 0.0002) and time point 'c' (p = 0.0003) in intragroup assessment.

i. Foul smell of mouth :

Foul smell of mouth in oral cavity cancer patients is associated with secondary infections in malignant lesions and inability to maintain oral hygiene during radiotherapy or due to ulcerative lesions. This condition is explained as Putimukha, a type of Mukharoga in Sushrut Samhita. Rakta Dushti and Tridosha Dusti are the important features of Putimukha Vyadhi. Nasya with Tikshna Dravya is recommended to treat Putimukha. Gandusha with Triphala and Haridra, which has anti-septic, anti-inflammatory, anti-microbial and anti-fungal activities are useful to treat foul smell of mouth.

In this study significant results are obtained for foul smell of mouth at time point 'b' ($p = 0.004$) in study group during intergroup assessment. In intragroup assessment extremely significant results are seen at time point 'b' ($p < 0.0001$) and 'c' ($p < 0.0001$) when compared with time point 'a', whereas similar results are obtained at only time point 'c' ($p = 0.0004$) in control group patients.

j. Debility :

Debility is a common symptom of all types of cancer. In oral cancer cavity patients, this symptom is seen in almost all patients due to hampered oral intake. Radiation induced stomatitis, xerostomia, trismus and dysphagia also leads to malnutrition and subsequently debility. Diagnosis of cancer and adverse effects of conventional treatment hamper quality of life of cancer patients and loses morale of the patient. Psychological stress in these patients is also responsible for debility.

In our study, extremely significant results are obtained in study group patients, who are treated with Basti, Nasya, Gandusha, Mukhapratisarana, Shirodhara and Karnapurana immediately after treatment (time point 'b') ($p = 0.0001$) and 1 month after treatment (time point 'c') ($p = 0.0001$), similar results are seen in intergroup analysis in study group at both time points i.e. time point 'b' ($p < 0.0001$) and time point 'c' ($p < 0.0001$) when compared with time point 'a'.

Snehana (Abhyanga) pacifies Vata Dosha, increases strength. Bala Taila is used for Snehana, which is indicated in debility. Ingredients of Bala Taila namely, Bala, Yava, Jatamansi, Shatavari, Punarnava and Godugdha possess Balya action. Matra Basti is

indicated in delicate patients and is effective to increase strength. Shirodhara with Jatamansi oil is useful in relieving mental stress and thus beneficial in stress induced debility. Jatamansi itself described as Balaprada i.e. effective in debility.

k. **Pain :**

Pain is an inevitable symptom of advance malignancies, especially of oral cavity cancers. Vitiation of Tridosha is responsible in pathogenesis of cancer. Thus various forms of pain, characteristic of each dosha are presented in advanced stage of cancer. In Vata dominance, pain is presented as pricking pain; in Pitta dominance, it is in form of burning sensation and in Kapha dominance it is dull aching pain.

Above all pain cannot be manifested without vitiation of Vata Dosha. Therefore treatment beneficial to pacify mainly Vata Dosha is a treatment of choice for pain management. Snehana (Abhyanga) with Bala oil is useful for pacifying Vata Dosha and thus pain caused due to its vitiation. Shula Shamana is one of the benefits of Swedana. Dashamoola decoction is used in our study for the purpose of Swedana. Ingredients of Dashamoola mainly pacify Vata Dosha, reduces swelling and pain. Basti is a treatment of choice of Vata Dosha. Matra Basti with Dashamoola oil is useful in pacifying Vata Dosha and relieving pain. Gandusha with Triphala and Haridra is beneficial in treating secondary infections of oral cavity, reducing inflammation and thus reduces pain. Mukhapratisarana with Yashtimadhu Ghruta reduces inflammation and pain caused due to it. Nasya and Karnapurana are indicated in pain in head and neck region. Very significant results are obtained in intergroup assessment at time point ‘b’ ($p = 0.002$) and ‘c’ ($p = 0.001$) for the symptom pain in study group. Extremely significant results are obtained at time point ‘b’ ($p < 0.0001$) and ‘c’ ($p<0.0001$) with respect to time point ‘a’ during intra-group assessment in study group.

CONCLUSION

1. Oral cavity cancer patients included in our study had maximum number of patients (54/70) above the age of 40 years (77%), maximum number of males (50/70, 71.43%), most of them were from middle socio-economic class (39/70, 55.71 %) and low socio-economic class (30/70, 42.86 %), having common sites of cancer as buccal mucosa and tongue (38/70, 54%) majority of them were in advanced stage of cancer i.e. stage III and IV (49/70, 70%), 62% (44/70) of them had grade II disease, 35% (25/70) among them were previously treated with radiotherapy alone and 45% (32/70) were treated with a combination of surgery and radiotherapy.
2. Patients of oral cavity cancer treated with Panchakarma Chikitsa in the form of Basti, Nasya, allied procedures like Gandusha, Mukha Pratisarana, Shirodhara and Karnapurana are highly effective in dysphagia and debility and effective in stomatitis and local pain immediately after completing treatment and even 1 month after completing treatment, indicating long lasting effect of these treatment modalities on above symptoms of oral cavity cancer. These treatment modalities are also effective in study group patient in symptoms of oral cavity cancer like xerostomia, excessive salivation, trismus and foul smell of mouth when assessed with their own condition / symptoms before starting treatment.
3. Treatment protocol of Panchakarma and allied procedures is highly effective in major symptoms of oral cavity cancers as well as in immediate and long lasting adverse effects of radiotherapy.
4. Quality of Life, which is usually remarkably hampered in oral cavity cancer patients, is significantly improved in patients treated with protocol of Basti, Nasya and allied procedures. Improvement in functional score, global score and symptom score which are the three components of Quality of Life questionnaire for cancer patients, assessed by themselves, is evident in study group patients treated with Panchakarma protocol and allied procedures indicating remarkable improvement in day-to-day well-being activities, social behaviors and aggressiveness of symptoms related to oral cavity cancer.

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WRITTEN INFORMED CONSENT FORM
CERTIFICATE BY INVESTIGATOR

I certify that I have disclosed all details about the study in the terms easily understood by the patient.

Date: Name of the Research Scholar:

Signature:

CONSENT BY SUBJECT

I have been informed to my satisfaction, by attending physician, the purpose of the clinical trial and the nature of drug treatment and follow up, including the laboratory investigations to be performed to monitor and safeguard my body function.

I am also aware of my right to opt out of the trial at any time during the course of trial without having to give the reason for doing so.

I, exercising my free power of choice, hereby give my consent to be included as a subject in clinical trial, "**Assessment of effectiveness of Basti, Nasya, Mukhopakrama, Shirodhara and Karnapurana on Quality of Life of oral cavity cancer patients** in the treatment of my disease.

Name of the Subject:

Signature or thumb impression:

Name of witness:

Signature or thumb impression

Relationship:

TILAK MAHARASHTRA VIDYAPEETH, PUNE

The Late Vaidya P.G. Nanal Department of Ayurveda

CASE RECORD FORM

Title - **Assessment of effectiveness of Basti, Nasya, Mukhopakrama, Shirodhara and Karnapurana on Quality of Life of oral cavity cancer patients**

Name of Scholar – Vd. Sushrut S Sardeshmukh

Name of Guide – Dr. Vineeta V. Deshmukh

Date: OPD No. :

Name of patient:

Address:

Contact No. :

Sex: Occupation:

Qualification:

Type of Work: Work Duration:

Vartaman Vyadhivrutta:

Purvavyadhi

Kulaja itihas - Swakula /Pitrukula /matrukula

Vyasan

Supari / Tambakhu / Vidi / Sigaret / Gutakha / Madhyapan / Others Praman :

Purva Chikitsa / Purva shastrakarma

Indriyaparikshan

Dnyanendriya -

Karmendriya –

•Strotas Parikshana-

1. Pranavaha strotas-

2. Udakvaha strotas-

3. Annavaha strotas

4. Rasavaha strotas

5. Raktavaha strotas

6. Mansavaha strotas

7. Medovaha strotas

8. Asthivaha strotas

9. Majjavaha strotas

10. Sukravaha strotas

11. Aartavaha strotas

12. Purisavaha strotas

13. Mutravaha strotas

14. Swadevaha strotas

•Nidanpanchak

1. Hetu

   Aaharaja -

   Viharaja

   Manasik

2. Purvarupa

3. Rupa

4. Upashaya / Anupshaya

5. Samprapti

   Chikitsa - Group –A/ Group B

Primary Examination -

B.P. - Pulse - Weight –

Mala – Mutra -

Jivha Parikshan –

Mukha Parikshan –

Ura Parikshan –

Udara Parikshan –

Assessment Criteria –

SR NO.	ASSESSMENT CRITERIA	TIME POINT a(0 DAY)	TIME POINT b (7^{TH} DAY)	TIME POINT c (1 month after time point b)
1	QLQ C30			
a	FUNCTIONAL SCORE			
b	GLOBAL SCORE			
c	SYMPTOM SCORE			
d	H & N 35 symptom score			
2	KARNOFSKY SCORE			
3	CANCER RELATED SYMPTOMS	GRADING		
A	Stomatitis			
B	Trismus			
C	Xerostomia			
D	Excessive salivation			
E	Dysphagia			
F	Foul smell from mouth			
G	Debility			
H	Pain			
I	Weight loss			

Signature of Guide

Signature of Student

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials: ⌊_⌊_⌊_⌊_⌋

Your birthdate (Day, Month, Year): ⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌋

Today's date (Day, Month, Year): 31 ⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌋

		Not at All	A Little	Quite a Bit	Very Much
1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2.	Do you have any trouble taking a long walk?	1	2	3	4
3.	Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4.	Do you need to stay in bed or a chair during the day?	1	2	3	4
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:

		Not at All	A Little	Quite a Bit	Very Much
6.	Were you limited in doing either your work or other daily activities?	1	2	3	4
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8.	Were you short of breath?	1	2	3	4
9.	Have you had pain?	1	2	3	4
10.	Did you need to rest?	1	2	3	4
11.	Have you had trouble sleeping?	1	2	3	4
12.	Have you felt weak?	1	2	3	4
13.	Have you lacked appetite?	1	2	3	4
14.	Have you felt nauseated?	1	2	3	4
15.	Have you vomited?	1	2	3	4
16.	Have you been constipated?	1	2	3	4

Please go on to the next page

During the past week:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

EORTC QLQ - H&N35

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week:		**Not at all**	**A little**	**Quite a bit**	**Very much**
31.	Have you had pain in your mouth?	1	2	3	4
32.	Have you had pain in your jaw?	1	2	3	4
33.	Have you had soreness in your mouth?	1	2	3	4
34.	Have you had a painful throat?	1	2	3	4
35.	Have you had problems swallowing liquids?	1	2	3	4
36.	Have you had problems swallowing pureed food?	1	2	3	4
37.	Have you had problems swallowing solid food?	1	2	3	4
38.	Have you choked when swallowing?	1	2	3	4
39.	Have you had problems with your teeth?	1	2	3	4
40.	Have you had problems opening your mouth wide?	1	2	3	4
41.	Have you had a dry mouth?	1	2	3	4
42.	Have you had sticky saliva?	1	2	3	4
43.	Have you had problems with your sense of smell?	1	2	3	4
44.	Have you had problems with your sense of taste?	1	2	3	4
45.	Have you coughed?	1	2	3	4
46.	Have you been hoarse?	1	2	3	4
47.	Have you felt ill?	1	2	3	4
48.	Has your appearance bothered you?	1	2	3	4

Please go on to the next page

During the past week:		**Not at all**	**A little**	**Quite a bit**	**Very much**
49.	Have you had trouble eating?	1	2	3	4
50.	Have you had trouble eating in front of your family?	1	2	3	4
51.	Have you had trouble eating in front of other people?	1	2	3	4
52.	Have you had trouble enjoying your meals?	1	2	3	4
53.	Have you had trouble talking to other people?	1	2	3	4
54.	Have you had trouble talking on the telephone?	1	2	3	4
55.	Have you had trouble having social contact with your family?	1	2	3	4
56.	Have you had trouble having social contact with friends?	1	2	3	4
57.	Have you had trouble going out in public?	1	2	3	4
58.	Have you had trouble having physical contact with family or friends?	1	2	3	4
59.	Have you felt less interest in sex?	1	2	3	4
60.	Have you felt less sexual enjoyment?	1	2	3	4

During the past week:		**No**	**Yes**
61.	Have you used pain-killers?	1	2
62.	Have you taken any nutritional supplements (excluding vitamins)?	1	2
63.	Have you used a feeding tube?	1	2
64.	Have you lost weight?	1	2
65.	Have you gained weight?	1	2

EORTC QLQ-C30 (version 3)

आपली व आपल्या आरोग्याविषयाची माहिती जाणून घेण्यास आम्ही उत्सुक आहोत. कृपया आपल्याला लागू पडणारी सर्व उत्तरे आपण स्वतः योग्य त्या आकडया भोवती वर्तुळ करून द्यावीत. ही उत्तरे बरोबर अथवा चुक या सदरात मोडत नाहीत. आपण पुरवलेली माहीती अतिशय गुप्त राखली जाईल.

आपल्या नावाची अद्याक्षरेः
जन्मतारीख (दिवस, महिना, वर्ष)ः
आजची तारीख (दिवस, महिना, वर्ष)ः ३१

		अजिबात नाही	थोडा	बराच	खूपच
१.	आपणास कष्टदायक काम करताना काही त्रास होतो का उदा. जड पिशवी किंवा सूटकेस उचलताना?	१	२	३	४
२.	आपणास जास्त लांब चाललयावर काही त्रास होतो का?	१	२	३	४
३.	आपणास घराबाहेर थोडे अंतर चालताना त्रास होतो का?	१	२	३	४
४.	आपणास दिवसभरात खुर्चीत बसून अथवा पलंगावर पडून राहण्याची गरज भासते का?	१	२	३	४
५.	आपणास जेवताना, कपडे घालताना स्नान करताना अथवा शौचादी कामासाठी मदत घ्यावी लागते का?	१	२	३	४

गेल्या आठवडयात

		अजिबात नाही	थोडा	बराच	खूपच
६.	आपले कामकाज अथवा इतर दैनंदिन व्यवहार करण्यावर काही बंधने आली का?	१	२	३	४
७.	आपले छंद पुरवण्यात अथवा फावल्या वेळातील उद्योग करण्यावर काही बंधने आली का?	१	२	३	४
८.	आपणास धाप लागली होती का?	१	२	३	४
९.	आपणास वेदना झाल्या होत्या का?	१	२	३	४
१०.	आपणास विश्रांतीची गरज भासली का?	१	२	३	४
११.	आपणास झोपेचा काही त्रास झाला होता का?	१	२	३	४
१२.	आपणास अशक्तपणा वाटला होता का?	१	२	३	४
१३.	आपली भूक मंदावली होती का?	१	२	३	४

गेल्या आठवडयात	अजिबात नाही	थोडा	बराच	खूपच
१४. आपणास मळमळल्यासारखे वाटले होते का?	१	२	३	४
१५. आपणास उलटया झाल्या होत्या का?	१	२	३	४
१६. आपणास बध्दकोष्ठतेचा त्रास झाला का?	१	२	३	४
१७. आपणास जुलाब झाले होते का?	१	२	३	४
१८. आपणास थकवा जाणवला का?	१	२	३	४
१९. वेदनेमुळे आपल्या दैनीक व्यवहारात अडथळा आला का?	१	२	३	४
२0. आपणास चित्त एकाग्र करणे कठीण गेले होते का, (उदा. पेपर वाचताना किंवा दूरचित्रवाणी बघताना)	१	२	३	४
२१. आपणास मानसिक ताण जाणवला का?	१	२	३	४
२२. आपण काळजी करत होता का?	१	२	३	४
२३. आपली चिडचिड झाली का?	१	२	३	४
२४. आपण उदास होता का?	१	२	३	४
२५. आपणास गोष्टी लक्षात ठेवण्यास त्रास झाला होता का?	१	२	३	४
२६. आपली शारीरिक स्थिती अथवा वैदयकिय उपचार यामुळे आपल्या कौटुंबिक जीवनात काही अडथळे आले का?	१	२	३	४
२७. आपली शारीरिक स्थिती अथवा वैदयकीय उपचार यामुळे आपल्या सामाजीक व्यवहारात काही अडथळे आले का?	१	२	३	४
२८. आपली शारीरिक स्थिती अथवा वैदयकिय उपचार यामुळे आपल्यापूढे आर्थिक अडचणी निर्माण झाल्या आहेत का?	१	२	३	४

खालील प्रश्नांची उत्तरे १ ते ७ पैकी आपल्याला लागू पडणा-या आकडया भोवती वर्तुळ करून द्यावीत.

२९. मागील आठवडयातील आपल्या सर्व साधारण आरोग्याचे मूल्यमापन आपण कसे कराल?

१	२	३	४	५	६	७
अति वाईट.						उत्कृष्ट.

३0. मागील आठवडयातील आपल्या जीवनाच्या दर्जाचे मूल्यमापन आपण कसे कराल?

१	२	३	४	५	६	७
अति वाईट.						उत्कृष्ट.

EORTC QLQ - H&N35

रूग्ण कधी त्यांना खालीलप्रमाणे त्रास होत आहे किंवा खालील लक्षणांपैकी काही लक्षणे दिसत आहे असे सांगत येतात. कृपा करून तुम्हाला खाली दिलेल्या लक्षणापैकी कोणत्या बाबतीत किती त्रास गेल्या आठवडयात झाला ते नमुद करा. ज्या प्रमाणात तुम्हाला त्रास झाला तो दर्शविणा-या आकडयाभोवती वर्तुळ करा

गेल्या आठवडयात	अजिबात नाही	जरासे	बरेच	खूप जास्त
३१. तुमच्या तोंडात दुखत होते का?	१	२	३	४
३२. तुमच्या जबडयात दुखत होते का?	१	२	३	४
३३. तुमचे तोंड आल्यासारखे वाटत होते का?	१	२	३	४
३४. तुमचा घसा दुखत होता का?	१	२	३	४
३५. पातळ पदार्थ गिळायला त्रास होत होता का?	१	२	३	४
३६. वाटून सरसरीत केलेले पदार्थ गिळायला अडचण आली होती का?	१	२	३	४
३७. घन अन्न पदार्थ गिळायला त्रास होत होता का?	१	२	३	४
३८. गिळताना घुसमटल्या सारखे वाटत होते का?	१	२	३	४
३९. तुम्हांला दातांचा काही त्रास झाला होता का?	१	२	३	४
४0. तोंड पूर्ण उघडायला त्रास झाला होता का?	१	२	३	४
४१. तोंड कोरडे पडत होते का?	१	२	३	४
४२. तुमची लाळ चिकट झाली होती का?	१	२	३	४
४३. वास घेण्याच्या क्षमतेमध्ये अडचण आली होती का?	१	२	३	४
४४. चव घेण्याच्या क्षमतेमध्ये अडचण आली होती का?	१	२	३	४
४५. खोकला आला होता का?	१	२	३	४
४६. आवाज घोगरा झाला होता का?	१	२	३	४
४७. तुम्हांला आजारी वाटत होते का?	१	२	३	४
४८. आपण कसे दिसतो याबद्ल चिंता वाटली होती का?	१	२	३	४

पुढील पानावर

गेल्या आठवडयात	अजिबात नाही	जरासे	बरेच	खुप जास्ती
४९. खाताना त्रास झाला होता का?	१	२	३	४
५0. कुटुंबियांसमोर खाताना त्रास झाला होता का?	१	२	३	४
५१. इतर माणसांसमोर खाताना त्रास झाला होता का?	१	२	३	४
५२. जेवणातील आनंद अनुभवताना त्रास वाटला होता का?	१	२	३	४
५३. दुस-यांबरोबर बोलताना त्रास होत होता का?	१	२	३	४
५४. टेलिफोनवर संभाषण करताना त्रास वाटला होता का?	१	२	३	४
५५. कुटुंबीयांबरोबर सामाजिक संबंध ठेवताना त्रास झाला होता का?	१	२	३	४
५६. मित्रमैत्रिणींबरोबर सामाजिक संबंध ठेवताना त्रास झाला होता का?	१	२	३	४
५७. बाहेर समाजात वावरताना त्रास झाला होता का?	१	२	३	४
५८. कुटुंबीयांसमवेत अथवा मित्रमैत्रिणींबरोबर शारिरीक जवळीक करताना काही त्रास वाटला होता का?	१	२	३	४
५९. लैंगिक जीवनातील आकर्षण कमी झाले आहे असे वाटले होते का?	१	२	३	४
६0. शरीर संबंधातील (संभोग) आनंदात कमीपणा आला आहे असे वाटले होते का?	१	२	३	४

गेल्या आठवडयात	नाही	होय
६१. वेदनाशामक गोळयांचा वापर केला होता का?	१	२
६२. (जीवनसत्वे सोडून) दुसरे काही पूरक अन्नघटक घेतले होते का?	१	२
६३. नळीद्वारा जेवण द्यावे लागले होते का?	१	२
६४. तुमचे वजन कमी झाले आहे का?	१	२
६५. तुमचे वजन वाढले आहे का?	१	२

Study Group

No.	Name	Age at diagnosis (Years)	Disease Index	Diagnosis	ICD code	Stage	Grade	Conventional treatment (Dates)
1	PS	59	145	Buccal Mucosa	C03	III	I	1) Surgery - a. Sep 2012 b. 06/05/2013 - WLE + MRND Marginal Mandibulectomy. C. 02/12/2013 - WLE + MRND 2) RT - 27/12/2013 to 06/01/2014 of total 5600 cGy and 31 # to face and neck
2	SF	73	143	Alveolus	C03	IV	II	1) Chemotherapy - 21/01/2013 to 07/03/2013 3 cycles of Paclitaxel and carboplatin, Inj. 5FU-D1-3 2) Surgery - 18/03/2013 Lt maxillectomy + Lt MRND + Lt radical forearm flap 3) RT- 21/01/2016 to 04/03/2016 5400 cGy 27 #.
3	LP	60	145	Buccal Mucosa	C06.0	I	II	1) Surgery - 21/10/2013 - WLE with left modified neck dissection with reconstruction of free radical artery forearm flap 2) RT - 30 # total 5400 cGy to left face and neck 13/01/2014 to 22/02/2014 3) Surgery - 28/05/2015 - WLE of recurrent rt buccal mucosa lesion + WLE of palate with nasolabial flap. 4) RT - 31 # total 55.8 Gy to right face and neck 02/07/2015 to 17/08/2015 5) Surgery - 17/12/2015 - WLE of recurrent buccal mucosa lesoin with infrastructure maxillectomy and upper alvelectomy.
4	RB	35	161	Post Cricoid	C13.0	II	II	1) RT - 32 # 31/03/2016 to 19/05/2016
5	SS	53	145	Buccal Mucosa	C06.0	III	II	1. RT - 19/12/2013 to 07/02/2014 31 #. 6200 cGy at L/R Lat face + Inj Cisplatin 50 mg/weekly (total 5 cycles taken -24/12/2013, 31/12/2013, 07/01/14, 14/01/14, 21/01/14. 2. Oral Chemo- Tab Erlotinib 150 mg OD since 10/01/2014 to 19/01/2014.

No.	Name	Age at diagnosis (Years)	Disease Index	Diagnosis	ICD code	Stage	Grade	Conventional treatment (Dates)
6	LK	58	143	Alveolus	C03	IV	II	1) Surgery - 26/03/2015 - WLE of lesion of right lower gingivo-lingula sulcus + FOM + Segmental Mandibulectomy + SOHND + free flap + STSG 2) RT - 19/11/2015 to 29/12/2015 total 6000 cGy to anterior neck.
7	KD	49	141	Tongue	C02.0	III	II	Radiation with concurrent Chemotherapy - 30 #, 60 Gy given to right neck from 29/01/2015 to 28/03/2015. 4 chemo cycles - Inj. Cisplatin (02/02/2015, 09/02/2015, 16/02/2015, 20/02/2015)
8	BR	35	161	Post Cricoid	C13.0	II	II	1) RT - 32 # 31/03/2016 to 19/05/2016
9	SH	47	161	Larynx	C32.0	III	II	RT - 30 # of total 6000 cGy at the neck region. 25/03/2016 to 10/05/2016
10	SSS	48	145	Buccal Mucosa	C06.0	IV	I	1) Surgery - 05/08/2016 WLE of left RMT + Left MND III + left free radical artery forearm flap reconstruction. 2) Radiation - 13/09/2016 to 27/10/2016, 30 #, 60 Gy given to face and neck
11	BT	77	161	Vocal Cord	C32.0	III	I	Radiation - 30 #, 6000 cGy at neck region from 05/01/2015 to 14/02/2015
12	PSS	69	140	Lip	C00.1	I	I	1) Surgery - 24/04/2017 WLE of Lower lip lesion with pri. Skin closure
13	LK	66	161	Vocal Cord	C32.0	I	I	1) Surgery - 17/06/2015 - Type I Cordectomy.
14	CP	56	141	Tongue	C02.0	IV	II	1) Surgery - 25/01/2017 WLE Lat. Border of tongue with supra omohyoid neck dissection. 2) RT - 15/02/2017 to 30/03/2017, 30 # 60 Gy to face and neck.
15	JK	70	145	Buccal Mucosa	C06.0	III	I	1) Surgery - 08/03/2017- Modified SOHD WLF 2 local excision Commando surgery. 2) RT - 20/03/2017 to 10/05/2017 , 30 # , 54 Gy to Rt. Face and neck.
16	MD	47	141	Tongue	C02.1	IV	I	1. Surgery = 13/11/2017 Extended Left Hemiglossectomy with B/L SOHD. 2. Radiation therapy = 30 #, 18/12/2017 to 01/02/2018 3. Adjuvant Chemotherapy = 6 cycles of Inj. Cisplatin 55 mg taken weekly from 18/12/2017 to 01/02/2018

No.	Name	Age at diagnosis (Years)	Disease Index	Diagnosis	ICD code	Stage	Grade	Conventional treatment (Dates)
17	SSS	53	145	Buccal Mucosa	C06.0	III	II	1. RT - 19/12/2013 to 07/02/2014 31 #. 6200 cGy at L/R Lat face + Inj Cisplatin 50 mg/weekly (total 5 cycles taken -24/12/2013, 31/12/2013, 07/01/14, 14/01/14, 21/01/14. 2. Oral Chemo- Tab Erlotinib 150 mg OD since 10/01/2014 to 19/01/2014.
18	KS	60	141	Tongue	C02.1	I	II	1) Surgery - 23/07/2017- WLE of ulcer with Primary A-P closure + Lt. RND. 2) RT - 31/07/2017 to 14/09/2017, 30 # 54 Gy at neck and neck nodes
19	SA	60	148	Pyriform fossa	C12	III	II	1. Surgery = Rt MRND with nodal clearance on 03/03/2016. 2. Radiation = 33 #, 6600 cGy givento face + neck from 11/04/2016 to 13/05/2016. Concurrent Chemotherapy - 6 weekly cycles of Inj. Cisplatin.
20	RK	49	141	Tongue	C02.1	IV	II	1. Surgery = Wide excision of tongue lesion with primary closure + left MNT on 25/09/2018. 2. Radiation = 34 #, 61.2 Gy, given to B/L Neck and Left neck nodal region from 22/10/2018 to 11/12/2018. Concurrent Chemotherapy = 7 cycles of Inj Cisplatin given weekly.
21	SM	50	141	Tongue	C02.1	II	II	1) Surgery - 03/03/2018- Hemiglossectomy. 12/05/2018 - Lt sub mandibular node dissection. 2) RT +Ct - 14/06/2018 to 25/07/2018, 30 # given to Lt. mandible + 5 # of weekly Cisplatin
22	BP	47	145	Buccal Mucosa	C06.0	IV	II	1. Surgery = Rt Buccal mucosa composite resection + Rt Marginal Mandibulectomy with B/L neck dissection on 29/01/2019. 2. Radiation = 30 #, 60 Gy given to B/L face and neck from 13/02/2019 to 27/03/2019. Concurrent Chemo = 6 weekly Cisplatin
23	SSS	53	145	Buccal Mucosa	C06.1	III	II	1. RT - 19/12/2013 to 07/02/2014 31 #. 6200 cGy at L/R Lat face + Inj Cisplatin 50 mg/weekly (total 5 cycles taken -24/12/2013, 31/12/2013, 07/01/14, 14/01/14, 21/01/14. 2. Oral Chemo- Tab Erlotinib 150 mg OD since 10/01/2014 to 19/01/2014.
24	LS	48	145	Buccal Mucosa	C06.2	I	II	1. RT = 14/04/2016 to 25/05/2016, 25 #, 5000 cgy to left cheek.
25	DB	68	148	Pyriform fossa	C12	III	II	Rt + CT = 07/07/2016 to 29/08/2016, 30 #, 6000 cGy given to neck and pyriform fossa + 4 cycles of weekly cisplatin.
26	TP	57	146	Oropharynx	C10.0	IV	II	RT + CT = 06/06/2016 to 02/08/2016, 30 #, 6000 cGy given to Oropharynx + 4 cycles of weekly cisplatin.

No.	Name	Age at diagnosis (Years)	Disease Index	Diagnosis	ICD code	Stage	Grade	Conventional treatment (Dates)
27	KS	60	141	Tongue	C02.1	I	II	1) Surgery - 23/07/2017- WLE of ulcer with Primary A-P closure + Lt. RND. 2) RT - 31/07/2017 to 14/09/2017, 30 # 54 Gy at neck and neck nodes
28	DG	50	148	Hypopharynx	C13.0	IV	III	1. Surgery = Tracheostomy under LA with total laryngectomy with partial pharyngectomy with radical neck dissection on 05/05/2016. 2. Radiation = 28 #, 5600 cGy given to B/L neck from 09/06/2016 to 18/07/2016. Concurrent Chemo = 5 weekly Cisplatin
29	BR	40	145	Buccal Mucosa	C06.0	II	II	1. Surgery = WLE of left Buccal Mucosa + Lt MND + Lt free forearm flap reconstruction. 2. RT = 01/08/2016 to 14/09/2016, 30 #, 6000 cGy to oropharynx and neck.
30	VM	52	161	Larynx	C14.0	IV	I	1. RT + CT = 22/03/2011 to 10/05/2011, 33 #, 66 Gy + 6 cycles of weekly Cisplatin
31	KM	42	145	Buccal Mucosa	C06.0	II	II	1) Surgery - 12/04/2019 Rt. side Hemimandibulectomy + WLE + PMMC + Rt. MRND 18/04/2019 - Rt Hemimandibulectomy with Rt. MRND. 2) RT- 03/06/2019 - 25 # OF 50 Gy to Rt face and neck. 18/07/2019 - 5 # of 10 Gy to tumour bed.
32	MS	51	161	Larynx	C32.0	III	II	1) RT + CT - 07/08/2019 to 25/09/2019, 35 #, 70 Gy to bilateral face and neck. Concurrent weekly 5 # of Cisplatin.
33	SG	45	145	RetroMolar Trigone	C06.2	II	II	1) RT- Inj Paclitaxel + Carboplatin on 17/04/2019 08/05/2019 01/06/2019 22/06/2019 2) RT - 17/07/2019 to 04/09/2019 70 Gy TO Rt side of face.
34	CB	72	145	Mandible	C41.1	III	III	1) RT - 18/10/2011 to 29/11/2019. total 6000 cGy 30 #, at Rt. And Lt. Mandible.
35	JK	38	141	Tongue	C02.1	IV	III	1) Surgery - 08/01/2011 Lt Hemiglossectomy with RND. 2) RT - 18/02/2011 to 01/04/2011.

No.	Name	Karnofsky score			Weight			Functional score			Symptom score			Global score			QLQ H&N35			Stomatitis			Trismus			Xerostomia			Excessive			Dysphagia			Foul smell			Debility			Pain		
		a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c
1	PS	90	100	100	62.1	61.2	61.5	93	100	100	13	5	0	75	83	83	40	36	35	1	0	0	0	0	0	1	1	0	0	0	0	1	1	0	0	0	0	1	0	0	1	0	0
2	SF	80	80	80	58	57.1	55.5	36	44	44	44	31	46	33	50	42	75	73	76	3	2	2	3	3	2	1	1	0	0	0	0	1	1	1	3	2	2	2	2	2	2	1	1
3	LP	80	90	90	57.2	56.8	57	96	100	100	15	3	0	83	100	100	54	49	47	2	1	1	2	1	1	0	0	0	0	0	0	2	1	1	0	0	0	1	1	0	1	1	0
4	RB	80	90	90	41	40.8	40.5	96	100	100	10	5	0	33	50	67	57	50	46	2	1	0	1	0	0	1	0	0	0	0	0	2	1	1	0	0	0	1	0	0	1	1	0
5	SS	80	80	90	69.2	68.5	68	67	71	80	31	15	13	50	67	67	61	57	55	2	1	1	2	1	1	0	0	0	1	1	1	0	0	0	2	1	1	2	1	1	2	2	1
6	LK	70	80	80	36.2	36	37	69	78	84	38	23	15	42	50	58	80	74	65	2	1	0	2	2	1	2	1	1	0	0	0	2	1	1	1	1	0	2	1	1	2	1	1
7	KD	70	90	100	72	71.8	71.5	91	91	91	5	3	3	92	100	100	50	44	41	2	1	1	2	1	1	2	2	1	0	0	0	0	0	0	1	0	0	1	0	0	2	1	1
8	BR	80	90	90	42.5	41	42.7	98	98	100	3	3	3	50	67	67	52	46	41	0	0	0	0	0	0	2	1	1	0	0	0	2	1	1	1	0	0	1	0	0	2	1	1
9	SH	80	90	80	61.7	61	59.5	71	78	73	31	28	23	50	50	50	61	42	40	1	0	0	0	0	0	1	1	0	0	0	0	2	1	2	0	0	0	1	0	1	3	2	2
10	SSS	80	90	90	55.1	54.8	55	69	87	89	21	15	10	50	50	67	80	56	50	2	1	0	2	1	1	2	2	1	0	0	0	0	0	0	0	0	0	1	1	0	2	1	1
11	BT	80	80	80	54.4	54	52.9	64	62	64	18	23	23	50	50	50	49	56	60	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	1	1	2	2	1	1
12	PSS	80	90	90	59.6	59.3	60	96	100	100	5	10	3	50	50	58	44	37	36	2	1	1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	0
13	LK	80	80	90	63	64.2	63.2	82	91	93	10	5	0	42	50	58	40	39	36	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
14	CP	90	90	90	56.2	57.1	58	89	80	93	8	8	3	83	83	100	51	53	43	2	1	1	2	1	1	1	1	0	1	0	0	2	1	1	0	0	0	0	0	0	1	1	0
15	JK	80	80	90	56.2	57	56.8	82	93	96	18	15	8	67	75	83	58	53	51	2	1	1	2	1	1	1	1	0	0	0	0	0	0	0	2	1	1	0	0	0	2	2	1
16	MD	80	90	90	67.2	65.9	66.5	91	96	100	23	15	3	58	67	83	60	57	46	0	0	0	0	0	0	0	0	0	2	1	1	2	1	1	0	0	0	0	0	0	2	1	0
17	SSS	80	90	90	67.2	66.1	66.5	82	84	89	10	8	5	42	50	58	45	48	45	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	1	0	0	1	1	0
18	KS	80	80	90	62	60	59.5	69	82	87	5	3	3	50	67	67	92	85	75	3	2	1	3	2	2	0	0	0	3	2	2	3	2	1	2	1	1	1	1	0	2	2	1
19	SA	90	100	100	80.5	77.1	78	100	100	100	3	0	0	100	100	100	35	35	35	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
20	RK	90	100	100	73.5	72.2	72.8	91	93	93	10	10	5	75	75	83	54	47	42	1	0	0	1	1	0	2	1	1	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0
21	SM	80	80	90	65.6	64.5	64.8	73	91	96	23	13	3	58	75	83	53	43	40	1	0	0	0	0	0	2	1	1	0	0	0	0	0	0	1	1	0	1	0	0	1	1	0
22	BP	90	100	100	49.4	48.5	49	93	96	98	5	3	0	83	100	100	45	42	41	1	0	0	1	0	0	2	1	1	0	0	0	2	1	1	1	0	0	0	0	0	2	1	1
23	SSS	70	80	80	69.6	67	67.5	84	91	91	5	5	5	58	67	75	40	42	45	2	1	0	1	1	1	0	0	0	1	0	0	0	0	0	1	0	0	1	0	0	2	1	1
24	LS	80	90	100	40.6	40.4	41.4	33	42	67	56	59	18	50	50	67	48	47	37	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	2	1	0	0	0	0	1	1	0
25	DB	80	90	90	68.2	69.3	69.6	89	80	84	5	10	5	58	50	58	40	38	38	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	1	0	0	1	1	0	1	1	0
26	TP	80	90	90	69.3	68.7	68.6	67	82	73	15	10	8	67	92	83	51	45	42	0	0	0	2	1	1	2	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
27	KS	80	90	90	67.3	66.2	65.9	84	91	84	10	10	8	58	50	67	45	46	39	1	0	0	0	0	0	2	1	0	0	0	0	0	0	0	1	0	0	0	0	0	2	1	1
28	DG	80	90	90	60.2	60.5	59.7	98	100	100	3	3	0	100	100	83	47	45	46	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	1	1	0	2	1	1
29	BR	90	90	90	75	74.2	76	100	100	100	0	0	0	67	75	83	35	35	35	1	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
30	VM	80	90	90	61.2	60.6	61	76	67	84	31	33	15	92	100	100	41	44	42	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	1	0	0	0	0	1	1	0
31	KM	80	90	90	70	70.7	71.7	60	71	78	49	26	21	67	67	75	85	79	70	2	1	1	2	1	1	2	1	1	0	0	0	0	0	0	1	0	0	1	0	0	2	1	1
32	MS	80	90	90	79	78	77.5	20	22	33	69	46	38	17	33	50	105	79	70	3	2	1	2	1	1	0	0	0	2	1	1	2	1	1	1	0	0	2	1	1	2	1	1
33	SG	80	80	80	56.5	56	55	64	98	82	31	28	36	67	50	33	110	107	110	2	1	1	4	4	3	0	0	0	2	1	1	1	1	1	1	1	1	2	1	1	3	2	2
34	CB	80	90	90	59.2	58.7	59	93	93	93	0	5	5	100	100	100	40	38	36	2	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	2	1	1
35	JK	80	80	90	68.7	68.2	68	76	82	89	0	0	5	100	100	100	85	63	40	1	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	1	0	0

Control Group

No.	Name	Age at diagnosis (Years)	Disease Index	Diagnosis	ICD code	Stage	Grade	Conventional treatment (Dates)
1	VB	41	141	Tongue	C02.1	III	III	SU - 24/11/2016-Total Glossectomy +Bil. Neck Dissection+FALT RT - 30/12/2016 to 18/2/2017 6000 cGy/30#
2	DD	81	161	Post Cricoid	C13.0	IV	III	RT - 1/10/2018 to 12/11/2018 5040cGy/28 # Concurrent CH - 4/10/2018 -Inj. Cisplatin 11/10/2018 to 8/11/2018 - Inj. Carboplatin
3	BH	71	145	Buccal Mucosa	C06.6	II	II	SU-24/5/2014 Rt. Hemimandibullectomy
4	GP	60	141	Tongue	C02.1	I	III	SU- Rt. Partial Glossectomy with Neck node dissection 8/12/2015
5	NS	64	161	Vocal Cord	C 32.0	III	III	SU - Rt. Hemi Larynyngiotomy+ B/L MND RT - 6600cGy/32 # 7/2/2017 to 23/3/2017
6	RK	61	161	Vocal Cord	C32.0	III	II	RT -21/9/2015 to 5/11/2015- 6600cGy/33#/6wks
7	DL	55	161	Epiglottis	C32.0	III	II	RT - 4/1/2016 to 25/2/2016 -7000cGy/35#
8	KS	40	145	Buccal Mucosa	C06.0	II	I	1. Surgery - 19/05/2017 - Lt. Hemimandebulectomy with MRND
9	VD	83	145	Buccal Mucosa	C06.0	IV	II	1. Surgery - 16/06/2015 - Left Commando (WLE of tumor + Hemimandibulectomy + Modified Neck Dissection) Post Commando Reconstruction with PMMC flap. 2. RT - 8 # , 4000 cGy from 19/11/2015 to 18/12/2015 to anterior neck and submental sol.
10	RP	52	145	Buccal Mucosa	C06.0	II	I	1. Surgery - a. 15/04/2011 - WLE right buccal mucosa (mandible preserved) - extended supraomohyoid neck dissection + radial artery based fore arm (left) micro-vascular flap (free flap) + SSG (skin grafting). b. 1/05/2011 - Reconstruction of right commisure suspension to mastoid fascia. 2. RT = 31/05/2011 to 08/07/2011, 30 #, 60 Gy.
11	MD	44	145	Cheek	C06.0	IV	II	1. Surgery - Bite Composite Resection + PMMC flap reconstruction. 2. RT - 29/12/2014 to 13/02/2015, 30 #, 6000 cGy to B/L face and neck
12	MG	55	143	Alveolus	C03.0	IV	II	1. Surgery - Right segmental mandible Commando Surgery + right neck dissection + Tracheostomy
13	SB	68	141	Tongue	C02.2	III	II	1. RT - 5/3/2015 to 14/4/2015, 30#, 6000 cGy to B/L oral and anterior lower neck. 2. Concurrent Chemotherapy = 5 cycles weekly of Inj. Cisplatin 50 mg with ECT from 09/03/2015 to 06/04/2015. 3. Chemotherapy - 6 cycles of Inj. Paclitaxel 300 mg + Inj. Methotrexate 50 mg from 29/06/2016 to 18/10/2016
14	VJ	60	161	Larynx	C32.0	III	II	1. RT with concurrent Chemotherapy = 26/04/2018 to 16/06/2018, 35#, 70 Gy given to neck + mediastinum

No.	Name	Age at diagnosis (Years)	Disease Index	Diagnosis	ICD code	Stage	Grade	Conventional treatment (Dates)
15	NS	60	145	Buccal Mucosa	C06.0	IV	II	1. Surgery - a. 24/10/2013 - WLE left buccal mucosa with collagen graft. b. 21/12/2013 - Left MND + Left nasolabial flap c. 06/10/2015 - Buccal mucosa excision + Marginal Mandibulectomy. d. 05/08/2016 - Right MND . 2. RT with chemo - 22/08/2016 to 15/10/2016, 31 #, 60 Gy. 4 chemo cycles weekly - Inj Docel 20 mg + Inj. Paliglob. 3. Oral Chemo - Geftinib 250 mg 1 OD since 27/12/2016 .
16	PG	54	140	Lip	C00.1	II	II	1. Surgery -21/08/2018 - Wide excision lip + leukoplakia fulguration + Modified neck dissection.
17	AW	58	161	Vocal Cord	C32.0	I	II	1. Surgery - a. 26/09/2012 - Rt Vocal Cordectomy b. 12/08/2015 - Type V Cordectomy
18	NP	40	141	Tongue	C02.1	IV	I	1. Surgery - Left Hemiglossectomy with left MND 2. RT with concurrent Chemo - 25#, 24/08/2017 to 28/09/2017 with 6 cycles of Inj. Cisplation weekly.
19	SK	61	145	Buccal Mucosa	C06.0	IV	II	1.Surgery - Left Mandibulectomy with left MRNA modified radical neck dissection with PMMNC flap. 2. RT - 21/01/2016 to 2/03/2016, 30 #,60 Gy to left buccal mucosa
20	PA	80	141	Tongue	C02.1	III	I	1. Chemotherapy - 8 cycles - 29/04/2016 to 29/12/2016 Inj Docetaxel 60 mg + Inj. 5 FU 400 mg + Inj. Cisplatin 20 mg
21	SK	48	141	Tongue	C02.1	IV	II	1. Surgery - Right Hemiglossectomy + right MND 2. RT - 5/10/2017 to 21/11/2017, 60 Gy, 30 # given to face and neck.
22	VJ	86	145	Buccal Mucosa	C06.0	III	II	1. RT - 06/11/2016 to 23/12/2016, 30 #, 6160 cGy given to left cheekc
23	DS	49	145	Buccal Mucosa	C06.0	II	II	1. Surgery - 01/09/2012 - Right cheek excision with Arch saving Mandibulectomy with Rt. MND. 2. RT - 18/10/2012 to 30/11/2012, 30#, 60 Gy

No.	Name	Age at diagnosis (Years)	Disease Index	Diagnosis	ICD code	Stage	Grade	Conventional treatment (Dates)
24	SS	70	148	Supra Glottis	C32.1	III	II	1. Surgery - Right Modified Radical Neck Dissection. 2. RT -13/08/2015 to 23/09/2015, 30 #, 6000 cGy to the Rt. Neck Recurrence 3. CT - I. 2 cycles (D1,D8,D15) Inj. Paclitaxel 90 mg + Inj. Carboplatin 150 mg from 08/06/2016 to 20/07/2016. II.6 cycles weekly Inj. Methotrexate 40 mg + Inj 5 FU 400 mg from 22/03/2017 to 12/05/2017
25	BM	73	146	Oropharynx	C10.0	III	III	1. RT- 29/10/2015 to 14/12/2015, 14 #, 5600 cGy to rt. Oropharynx and Rt neck.
26	GP	41	141	Tongue	C02.1	III	II	1. Surgery - Lt wide Excision - Glossectomy + Lt MND 2. RT- 29/10/2018 to 13/12/2018. 30 # + 3 weekly Chemo Inj Cisplatin 50 mg (30/10/2018 to 12/11/2018)
27	PR	37	145	Buccal Mucosa	C06.0	III	I	1. Surgery- WLE Lt BM lesion + Lt. Hemimandibulectomy + lt MND + PMMC flap reconstruction 2. RT - 05/10/2017 to 17/11/2017, 30 #, 60 cGy to tumor bed and bilateral neck + weekly 6 cycles of Inj. Cisplatin 70 mg
28	BF	66	161	Larynx	C32.0	III	II	1. RT - from 23/12/2011 to 26/01/2012 , 26 #, 5200 cGy. 2. Chemotherapy - 28/12/2011 to 25/01/2012, 5 cycles of Inj. Cisplatin 50 mg each.
29	JK	58	145	Buccal Mucosa	C06.0	III	I	1. Surgery -25/11/2011 WLE Ulcer with grafting + Rt RND 2. RT - 21/12/2011 to 02/02/2012, 30# 60 cGy to Rt. Cheek and neck + 6 cycles of weekly Inj. Cisplatin 50 mg 3. Surgery - 08/10/2015 , WLE Cheek tumor + Rt. Hemimabdibulectomy with skin grafting. 4. RT- 02/11/2015 to 20/12/2015 5. Chemotherapy - 26/04/2016 to 18/06/2016, 3 cycles of Inj. Cisplatin 110 mg + Docetaxel 110 mg.
30	DN	34	161	Larynx	C32.0	IV	I	1. Chemotherapy - 2 cycles, Inj Paclitaxel 230 mg + Inj. Carboplatin 620 mg, 22/07/2016 , 03/09/2016. 2. Oral chemo - From 21/10/2016, Tab Geftinate 250 mg OD, Tab Methotrexate 2.5 mg OD RT - 10 #, 30 Gy from 22/03/2017 to 05/04/2017

No.	Name	Age at diagnosis (Years)	Disease Index	Diagnosis	ICD code	Stage	Grade	Conventional treatment (Dates)
31	TK	47	145	Retro Molar Trigone	C06.2	I	III	1. Surgery - 13/05/2015- Rt PSM + SND + reconstruction with Lt. FFOCF 2. RT with CT - 17/06/2015 to 29/07/2015, 30 #, 60cGy to Rt level I to V LNs + 6 cycles weekly Inj. Cisplatin 45 mg.
32	SL	28	160	Maxilla	C31.0	II	III	1. Surgery - 18/11/2013 Surgical excision 2. RT- 12/12/2013 to 30/01/2014, 31 # , 6200 cGy at maxillary region.
33	PG	60	141	Tongue	C01	IV	II	1. CT- April 2011 to June 2011, 3 cycles, Inj Paclitaxel 300 mg + Inj. Cisplatin 110 mg . 2. RT - 08/07/2011 to 25/08/2011, 25 # 5000 cGy to tongue and neck LNs.
34	MP	65	161	Epiglottis	C32.0	III	II	1. RT + CT - 22/03/2012 to 06/06/2012, 33 # + 5 cycles weekly Inj. Cisplatin 40 mg.
35	RK	38	145	Buccal Mucosa	C06.0	IV	III	1. Surgery - 22/11/2012- Lt upper alveolectomy with infrastructural Maxillectomy + Lt. SOHD. 18/04/2013- Rt. MRND (Rt. Level II B neck node mets) 2. RT + CT - 19/12/12 to 08/02/2013, 30 #, 60 Gy + 5 cycles Injection Cisplatin 43 mg weekly. 3. RT - 11/05/2013 to 14/06/2013, 25 # 50 Gy to Rt. neck

No.	Name	Karnofsky score			Weight			Functional score			Symptom Score			Global score			QLQ H&N35			Stomatitis			Trismus			Xerostomia			Excessive salivation			Dysphagia			Foul smell of mouth			Debility			Pain		
		a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c
1	VB	80	80	80	69	69	68	53	56	67	28	23	15	50	50	58	88	84	82	2	2	2	2	2	2	2	2	1	0	0	0	2	2	1	2	2	1	2	2	1	2	2	2
2	DD	60	60	50	55	54	52	38	44	40	44	36	46	33	50	42	84	81	86	3	2	2	1	1	1	2	2	1	0	0	0	2	2	2	0	0	0	2	2	2	4	4	4
3	BH	70	80	80	84	85	87	67	71	84	31	28	21	58	67	67	56	53	48	1	1	0	2	1	1	2	1	1	0	0	0	1	1	1	1	1	0	1	1	0	1	1	0
4	GP	80	90	90	72	71	72	78	82	89	26	21	10	58	67	83	49	46	42	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
5	NS	70	70	80	73	73	73	76	80	84	13	13	8	50	58	58	54	51	50	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	1	1	1	1	1	0
6	RK	70	80	70	58	58	57	76	80	73	28	26	26	58	67	67	62	60	64	0	0	0	0	0	0	2	2	2	0	0	0	2	1	2	0	0	0	2	1	2	2	2	3
7	DL	70	70	80	64	64	65	76	73	78	13	13	10	67	67	67	54	51	50	0	0	0	1	1	1	1	1	1	0	0	0	0	1	0	0	0	0	1	1	0	0	1	0
8	KS	80	80	80	62	62	62	84	91	93	54	49	49	50	58	58	43	42	42	2	1	1	1	1	1	0	0	0	1	1	1	1	1	1	1	1	0	1	1	1	2	2	1
9	VD	70	70	60	41	42	40	40	44	44	44	41	44	25	33	33	74	68	72	3	3	2	1	1	1	0	0	0	3	2	3	2	2	2	3	2	2	3	2	1	4	4	4
10	RP	70	70	80	48	47	46	89	93	93	26	18	15	67	75	75	56	54	50	2	2	2	2	2	2	1	1	1	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1
11	MD	70	70	70	58	58	59	62	60	56	44	36	41	50	50	50	65	62	63	2	2	2	2	2	2	0	0	0	0	0	0	1	1	1	2	2	1	2	2	1	2	2	2
12	MG	70	70	70	66	65	65	62	67	71	49	44	31	50	50	50	75	73	69	1	1	1	2	2	2	0	0	0	2	2	1	1	1	1	1	1	1	1	1	1	2	2	1
13	SB	70	70	60	44	44	43	84	84	80	15	15	21	67	67	50	60	67	69	0	0	0	1	1	1	2	2	2	0	0	0	2	2	2	0	0	0	2	2	2	2	1	2
14	VJ	80	80	90	60	60	61	76	80	82	21	18	13	50	50	58	53	47	45	1	1	0	1	1	0	1	1	0	0	0	2	2	1	0	0	0	0	0	0	0	1	1	0
15	NS	80	80	90	66	66	66	80	91	93	26	21	15	50	50	67	70	60	62	2	2	1	1	1	1	2	2	1	0	0	0	1	1	1	2	1	1	2	2	1	1	1	1
16	PG	70	80	80	87	87	88	91	93	89	8	8	13	50	50	50	51	48	55	2	2	1	1	0	0	0	0	0	1	0	0	0	0	0	1	1	0	1	1	0	1	1	2
17	AW	80	80	80	70	71	72	84	89	89	13	10	5	58	67	67	42	43	40	0	0	0	0	0	0	1	1	1	0	0	0	1	0	0	0	0	0	1	0	0	1	1	0
18	NP	70	70	80	60	60	61	67	73	78	18	13	8	67	67	75	59	55	51	2	2	1	2	2	2	2	2	1	0	0	0	2	2	2	1	1	0	1	1	0	1	1	1
19	SK	70	70	70	62	62	62	71	76	76	23	21	15	50	58	67	62	58	52	2	2	2	3	3	2	1	1	1	0	0	0	2	2	1	1	1	1	1	1	1	2	2	1
20	PA	70	70	60	62	61	57	80	82	78	13	8	18	42	50	50	60	62	70	2	2	3	2	2	2	1	1	1	0	0	0	2	2	2	2	2	2	2	2	3	2	2	2
21	SK	60	60	70	51	50	49	71	78	84	36	33	28	50	50	50	62	58	55	1	0	0	2	2	1	1	1	1	0	0	0	2	2	2	1	1	1	2	2	2	2	2	1
22	VJ	80	80	90	37	37	38	80	84	89	23	21	15	58	58	67	55	53	50	2	2	1	0	0	0	2	2	1	0	0	0	1	1	1	1	1	0	1	1	1	1	1	1

No.	Name	Karnofsky score			Weight			Functional score			Symptom Score			Global score			QLQ H&N35			Stomatitis			Trismus			Xerostomia			Excessive salivation			Dysphagia			Foul smell of mouth			Debility			Pain		
		a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c
23	DS	90	90	90	71	71	72	93	98	##	0	0	0	67	75	83	40	38	35	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0
24	SS	80	70	60	41	41	40	64	71	73	31	26	28	50	50	50	60	58	64	2	2	2	0	0	0	2	1	1	0	0	0	2	2	2	0	0	0	2	2	3	3	3	4
25	BM	70	60	60	39	38	36	51	47	49	33	44	54	33	33	33	78	80	84	0	0	0	1	1	1	0	0	0	0	0	0	3	3	3	0	0	0	3	3	3	4	4	4
26	GP	80	90	90	78	79	78	76	80	82	18	13	8	50	58	67	55	51	47	2	2	1	1	1	1	2	2	1	0	0	0	2	2	2	1	1	0	1	1	1	1	1	1
27	PR	##	##	##	75	75	75	98	##	##	18	0	0	75	75	83	37	35	35	0	0	0	1	1	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
28	BF	80	90	90	63	62	62	56	64	67	33	38	31	67	67	83	48	46	43	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	1	1	0	1	1	0
29	JK	60	60	60	46	45	44	42	49	40	33	54	69	33	33	33	82	80	84	2	2	1	2	1	1	0	0	0	3	2	2	2	2	2	2	2	1	2	2	2	2	2	2
30	DN	60	60	60	38	37	37	80	18	16	33	64	72	33	33	33	98	91	##	2	3	2	0	0	0	1	1	1	0	0	0	3	3	3	0	0	0	3	3	3	2	2	2
31	TK	70	70	80	45	45	46	80	87	91	33	5	3	90	50	50	48	42	40	1	1	1	1	1	1	2	2	1	0	0	0	0	0	0	0	0	0	1	1	1	3	3	2
32	SL	80	80	90	53	53	53	80	89	91	33	3	3	83	83	83	44	42	39	1	1	1	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1	1	0	1	1	1
33	PG	80	90	90	57	57	57	80	76	84	33	5	3	83	92	##	45	44	42	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
34	MP	80	80	80	33	33	33	80	78	80	33	21	15	90	58	75	56	55	52	2	2	2	1	1	1	1	1	1	0	0	0	2	2	2	0	0	0	2	2	2	2	2	2
35	RK	80	80	80	48	47	48	80	64	67	33	31	23	90	42	42	58	55	55	2	2	1	0	0	0	2	2	1	0	0	0	0	0	0	0	0	0	2	1	0	2	1	1

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CERTIFICATE OF ANALYSIS

(Finished Product)

Name of Product	: A.Gandush Churna	**FP Code**	: FP163
Batch no.	: PR03/16	**Batch Quantity**	: 2.450 kg
Mfg. Date	: 08-2016	**Best before Dt**	: 07-2018
Sampled Qty	: 100 gm	**Sampling date**	: 05/08/16
Analysis date	: 05/08/16	**Reporting date**	: 05/08/16

S.N.	Test	Result	Specification
1.	Description	Greenish Yellow colored coarse powder with astringent taste.	Greenish Yellow colored coarse powder with astringent taste.
2.	Loss on drying	0. 4628 %w/w	Not More Than 05 %w/w
3.	pH (10 % w/v solution)	4.38	4-5

Remark: The above sample complies/Not complies as per IHS

Analyzed by:

For Atharva

Approved by:

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CERTIFICATE OF ANALYSIS

(Finished Product)

Name of Product	: Bala Tail	**FP Code**	: FP170
Batch no.	: PR01/16	**Batch Quantity**	: 29.5 Lit
Mfg. Date	: 07-2016	**Best before Dt**	: 06-2019
Sampled Qty	: 100 ml x 2	**Sampling date**	: 23/07/16
Analysis date	: 23/07/16	**Reporting date**	: 23/07/16

S.N.	Test	Result	Specification
1.	Description	Yellowish brown colored oil with aromatic odour.	Yellowish brown colored oil with aromatic odour.
2.	Agni Pariksha(Flame Test)	Positive	Kalka burn without crackling sound when exposed to flame.
3.	Varti Pariksha (Wick Test)	Positive	Kalka becomes harder and rolls in to Varti (Wick).
4.	Fena Pariksha (Foam Test)	Positive	Foam will appear over the Taila.
5.	Weight per ml	0.9145 gm/ml	0.9100 – 0.9200 gm/ml
6.	Refractive Index	1.4655	1.464-1.466

Remark: The above sample complies/Not complies as per IHS

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CERTIFICATE OF ANALYSIS

(Finished Product)

Name of Product	: Dashmool Bharad Churna	**FP Code**	: FP165
Batch no.	: PR01/16	**Batch Quantity**	: 9.850 kg
Mfg. Date	: 05-2016	**Best before Dt**	: 04-2018
Sampled Qty	: 100 gm	**Sampling date**	: 28/05/16
Analysis date	: 28/05/16	**Reporting date**	: 29/05/16

S.N.	Test	Result	Specification
1.	Description	It consists of coarse powder of Dashmool.	It consists of coarse powder of Dashmool.
2.	Loss on drying	0.4473 %w/w	Not More Than 05 %w/w
3.	Total Ash	4.0639 % w/w	Not More Than 8 % w/w
4.	Acid Insoluble Ash	1.1024 % w/w	Not More Than 3 % w/w
5.	Alcohol Soluble Extractive	30.2015 % w/w	Not Less Than 28 % w/w
6.	Water Soluble Extractive	34.3022 % w/w	Not Less Than 32 % w/w

Remark: The above sample complies/Not complies as per IHS

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CERTIFICATE OF ANALYSIS

(Finished Product)

Name of Product	: A. Dashmool Tail	**FP Code**	: FP031
Batch no.	: PR01/16	**Batch Quantity**	: 39.2 Lit
Mfg. Date	: 01-2016	**Best before Dt**	: 12-2018
Sampled Qty	: 100 ml x 2	**Sampling date**	: 16/01/16
Analysis date	: 16/01/16	**Reporting date**	: 16/01/16

S.N.	Test	Result	Specification
1.	Description	Yellowish brown colored oil with specific odour.	Yellowish brown colored oil with specific odour.
2.	Agni Pariksha(Flame Test)	Positive	Kalka burn without crackling sound when exposed to flame.
3.	Varti Pariksha (Wick Test)	Positive	Kalka becomes harder and rolls in to Varti (Wick).
4.	Fena Pariksha (Foam Test)	Positive	Foam will appear over the Taila.
5.	Weight per ml	0.9159 gm/ml	0.9100 – 0.9200 gm/ml
6.	Refractive Index	1.4645	1.463-1.466

Remark: The above sample complies/Not complies as per IHS

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CERTIFICATE OF ANALYSIS

(Finished Product)

Name of Product	: A. Jatamansi Tail	**FP Code**	: FP034
Batch no.	: PR01/16	**Batch Quantity**	: 27.5 Lit
Mfg. Date	: 01-2016	**Best before Dt**	: 12-2018
Sampled Qty	: 100 ml x 2	**Sampling date**	: 15/01/16
Analysis date	.: 15/01/16	**Reporting date**	: 15/01/16

S.N.	Test	Result	Specification
1.	Description	Yellowish brown colored oil with aromatic odour.	Yellowish brown colored oil with aromatic odour.
2.	Agni Pariksha(Flame Test)	Positive	Kalka burn without crackling sound when exposed to flame.
3.	Varti Pariksha (Wick Test)	Positive	Kalka becomes harder and rolls in to Varti (Wick).
4.	Fena Pariksha (Foam Test)	Positive	Foam will appear over the Taila.
5.	Weight per ml	0.9166 gm/ml	0.9100 – 0.9200 gm/ml
6.	Refractive Index	1. 465	1.464-1.466

Remark: The above sample complies/Not complies as per IHS

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CERTIFICATE OF ANALYSIS

(Finished Product)

Name of Product	: A. Yashtimadhu Ghrut	**FP Code**	: FP030
Batch no.	: PR01/16	**Batch Quantity**	: 39.2 kg
Mfg. Date	: 02-2016	**Best before Dt**	: 01-2018
Sampled Qty	: 70 gm x 2	**Sampling date**	:30/01/16
Analysis date	: 01/02/16	**Reporting date**	: 01/02/16

S.N.	Test	Result	Specification
1.	Description	Yellow colored Ghruta with characteristic odour of Yashtimadhu.	Yellow colored Ghruta with characteristic odour of Yashtimadhu.
2.	Agni Pariksha(Flame Test)	Positive	Kalka burn without crackling sound when exposed to flame.
3.	Varti Pariksha (Wick Test)	Positive	Kalka becomes harder and rolls in to Varti (Wick).
4.	Fena Pariksha (Foam Test)	Positive	Foam should be disappearing over the Ghruta.

Remark: The above sample complies/Not complies as per IHS

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CERTIFICATE OF ANALYSIS

(Finished Product)

Name of Product	: A. Yashtimadhu Tail	**FP Code**	: FP032
Batch no.	: PR01/16	**Batch Quantity**	: 32 Lit
Mfg. Date	: 02-2016	**Best before Dt**	: 01-2019
Sampled Qty	: 100 ml x 2	**Sampling date**	: 12/02/16
Analysis date	: 12/02/16	**Reporting date**	: 12/02/16

S.N.	Test	Result	Specification
1.	Description	Yellowish brown colored oil with specific odour of Yshtimadhu.	Yellowish brown colored oil with specific odour of Yshtimadhu.
2.	Agni Pariksha(Flame Test)	Positive	Kalka burn without crackling sound when exposed to flame.
3.	Varti Pariksha (Wick Test)	Positive	Kalka becomes harder and rolls in to Varti (Wick).
4.	Fena Pariksha (Foam Test)	Positive	Foam will appear over the Taila.
5.	Weight per ml	0.9138 gm/ml	0.9100 – 0.9200 gm/ml
6.	Refractive Index	1.464	1.464-1.466

Remark: The above sample complies/Not complies as per IHS

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