

**“EFFICACY OF HOMOEOPATHY FOR IMPROVING THE
QUALITY OF LIFE IN ORAL CANCER PATIENTS”.**

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE
REQUIREMENT

FOR THE AWARD OF THE DEGREE OF

DOCTOR OF MEDICINE IN HOMOEOPATHY: M.D. (Hom.)

IN

PRACTICE OF MEDICINE

By

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UNDER THE GUIDANCE OF

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**SARADA KRISHNA HOMOEOPATHIC MEDICAL COLLEGE,
KULASEKHARAM, TAMIL NADU**



SUBMITTED TO

THE TAMILNADU Dr. MGR MEDICAL UNIVERSITY, CHENNAI

**ENDORSEMENT BY THE HEAD OF THE DEPARTMENT
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This is to certify that the Dissertation entitled “**EFFICACY OF HOMOEOPATHY FOR IMPROVING THE QUALITY OF LIFE IN ORAL CANCER PATIENTS**” is a bonafide work carried out by **Dr. RAJESH R.S.**, a student of M.D.(Hom.) in **DEPARTMENT OF PRACTICE OF MEDICINE** in SARADA KRISHNA HOMOEOPATHIC MEDICAL COLLEGE under the supervision and guidance of **Dr. N. V. SUGATHAN M.D.(Hom.)**, **Prof. Department of Practice of Medicine** in partial fulfilment of the Regulations for the award of the Degree of **DOCTOR OF MEDICINE(HOMOEOPATHY)** in **PRACTICE OF MEDICINE**. This work confirms to the standards prescribed by THE TAMILNADU DR. MGR MEDICAL UNIVERSITY, CHENNAI.

This has not been submitted in full or part for the award of any degree or diploma from any University.

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DECLARATION

I, **Dr. RAJESH R.S.** do hereby declare that this Dissertation entitled **“EFFICACY OF HOMOEOPATHY FOR IMPROVING THE QUALITY OF LIFE IN ORAL CANCER PATIENTS”**. is a bonafide work carried out by me under the direct supervision and guidance of **Dr. N. V. SUGATHAN, M.D.(Hom.)** Prof. Dept. of Practice of Medicine, in partial fulfillment of the Regulations for the award of degree of **Doctor of Medicine (Homoeopathy)** in **PRACTICE OF MEDICINE** of The Tamil Nadu Dr. MGR Medical University, Chennai. This has not been submitted in full or part for the award of any degree or diploma from any University.

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ABSTRACT

INTRODUCTION:

The quality of life is an indicator of improvement of the cancer treatment which includes analysis of the life quality as a parameter of cancer management. This clinical study was aimed at checking the effectiveness of homoeopathic medicines in improving the quality of life in oral cancer patients using before and after value.

MATERIALS AND METHODS:

A sample of 30 cases above 18 yrs of age suffering from oral cancer were selected from the OPD/ IPD of Sarada Krishna Homoeopathic Medical College Hospital and its peripheral health centers. The cases were taken in pre structured standardised Sarada Krishna chronic case record and medicines were selected based on totality. Before giving the medicine life quality score was marked using the quality of life chart (EORTC QLQ H&N 43) which is specific for head and neck region cancer. After the administration of Homoeopathic medicines, the cases were regularly assessed on a monthly basis or as per the need of the case at least six months and the prognosis were assessed. Paired “t” test was applied for analysing the difference before and after treatment.

RESULT AND CONCLUSION:

According to the improvement of quality of life after treatment, the study population is categorised under the headings Aggravation (0%), No change(13.33%), No significant improvement(3.33%), Mild improvement(36.67%), Moderate improvement(20%), Marked improvement(26.67%). The statistical analysis shows that, the Stat t value 7.53., proving the result that homoeopathic medicines have significant effect in improving quality of life of patients with oral cancer.

KEY WORDS: oral cancer ,paired t test, quality of life, homoeopathy.

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Dr. RAJESH R.S.

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LIST OF ABBREVIATIONS USED

SL. NO.	ABBREVIATION	EXPANSION
1.	%	Percentage
2.	<	Aggravation
3.	>	Amelioration
4.	=, A/F	Ailments from
5.	D	Dose
6.	Dr	Doctor
7.	F	Female
8.	M	Male
9.	H/O	History of
10.	No.	Number
11.	OPD	Outpatient department
12.	S.No.	Serial Number
13.	IPD	In patient department
14.	SL	SaccharumLactis
15.	§	Aphorism
16.	yrs	Years
17.	wks	Weeks
18.	C/O	Care of
19.	Kgs	Kilograms
20.	i.e.,	That is

21.	eg.	Example
22.	H&N	Head and neck
23.	QLQ	Quality of life questioner
24.	Σ	Sum
25.	m	Meter
26.	BQ	Betel Quid
27.	TSNA	Tobacco-specific nitrosamines
28	ROS	Reactive oxygen species
30	AN	Areca nut
31	HPV	Human Papilloma virus
32	HNSCC	Head and Neck Squamous Cell Carcinoma
33	HHV	Human Herpes virus
34	OSCC	Oral squamous cell carcinoma
35	IL-6	Interleukin 6
36	DNA	De-riboxi Nucllic acid
37	NOTCH	Notch homologues are translocation- associated
38	EGFR	epidermal growth factor receptor
39	TME	Tumor micro environment
40	CAFs	Cancer-associated fibroblasts
41	EORTC	European organization for research and treatment of cancer

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1.0 INTRODUCTION

Oral cancer is an antique disease, In Sushruta Samhitha even give the description of oral cancer in India. Its aggressiveness and local involvement of surrounding structure disfiguration and functional affection lead to physiological and psychological discomfort ultimately affecting the quality of life¹. The term ‘malignant disease’ encompasses a wide range of illnesses; it is second only to cardiovascular disease as the cause of death. Oral cancer one of the leading morbidity and mortality in India like developing countries and tobacco is one of the major causative factor of the disease. In India tobacco use incredible linked to poverty and health issue along with lack of medical facilities, primary care and screening tools especially in rural areas contribute the high oral cancer incidences¹. Oral cancer is any malignant changes which are found on the lip, floor of the mouth, cheek lining, gingival, palate or in the tongue. Oral cancer is among the top three types of cancers in India².

Oral cancer is of significant public health importance to India. Firstly, it is diagnosed at later stages and not have proper treatment adopted especially the rural areas and low social economic group. As a result, delay has also been largely associated with advanced stages of oral cancer. Earlier detection of oral cancer offers the best chance for long term survival³. But the precipitating factor like the scio-economic status, habbit and health care thereby reducing chances of survival. Public health officials, private hospitals, and academic medical centres within India have recognized oral cancer as a grave problem³.

Even though medical system is advanced and facilities are increased, the disease burden increasing the day to day. In there the scope of alternating system can utilized and prove its efficassy.

Homoeopathy the world's second most system of treatment have its own peculiarity and proven its successiveness in so many time. Homoeopathy is a system with a wide range of medicines suitable for both acute and chronic medical conditions. Medicine can act acutely based on symptom similarity on par with the conventional medicine on the basis of 'like cures like'. When homoeopathic medicines are administered, medicines not only annihilate the presenting symptoms but also prevent the further prognosis of disease. In early dictated cases our system can produce marked changes in most reliable and economic way. Even if many result are obtained in cancer treatment but need scientific study in specific cancers. The high incidence rate and socio economic, cultural, environmental, habitual like precipitating factors all are present in the locality so we utilize our system as maximum against oral cancer along with that study about the efficacy.

2.0 AIMS AND OBJECTIVES

- To know the effect of homoeopathic medicine in improving Quality of Life (QoL) in cancer patients.
- To know the commonly used homoeopathic medicines for the treatment of oral cancer.

3.0 REVIEW OF LITERATURE

Definition:

Cancer is defined as uncontrollable growth of cells which tend to proliferate in an uncontrolled way and, in some cases to metastasize and cause to damage to surrounding tissue⁴. Oral cancer is a growth of malignant cells in any part of the oral cavity which include the lip, tongue, hard and soft palate, salivary gland, lining of cheek, floor of mouth or under the gum, tongue and teeth⁵.

Epidemiology

In India Every year 11,57,294 lakh new cancer cases are reporting and Cancer related deaths are around 7,84,821 peoples⁶. Risk of developing cancer before the age of 75 years Male: 9.81% ,Female: 9.42%. and oral cancer is the most common cancer in the mans in india⁷ 1,19,992 of new cases are reported and 72,616 deaths are occur in recent year. Around 80-90% of oral cancers are directly attributable to tobacco use⁸: In general awareness about the oral cancer is very poor in these rural areas in South India⁹ and there is a need to device public health Programme to improve the awareness and active screening of high risk population in rural areas area¹⁰. In general the awareness about the oral cancer is poor in rural villages in India. Cancer screening programmers should be actively done among high risk populations in rural villages, in India.

Distribution of the standardized incidence rate of oral cavity and Lips cancer in the world

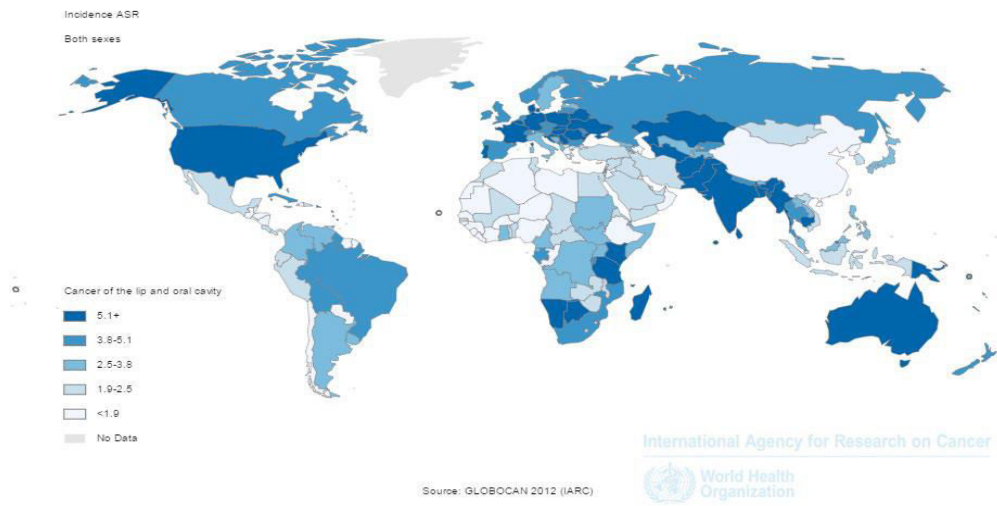


Figure-1

Varying trends of cancer in 2007,2011 and 2016

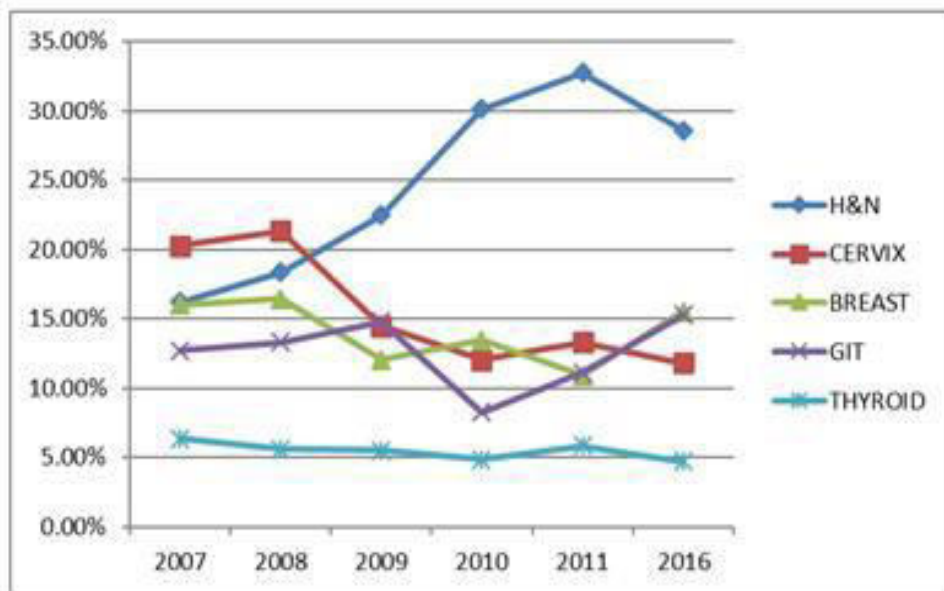


Figure-2

The term oral cavity refers to lips, buccal mucosa, alveolar ridges, retro molar trigon, hard palate, floor of the mouth and anterior two-thirds of the tongue. Oral cancer or oral cavity cancer, a subtype of head and neck cancer¹², is any cancerous tissue growth located in the oral cavity. The types of oral cancers, are squamous cell carcinomas, basal cell carcinomas, verrucous carcinomas, nasopharyngeal carcinomas, malignant melanoma, Ameloblastoma, mucoepidermoid carcinoma, and so on¹³; in this majority are squamous cell carcinomas and around 90% are squamous cell carcinomas, originating in the tissues that line the mouth and lips.. Oral or mouth cancer most commonly involves the tongue. It may also occur on the floor of the mouth, cheek lining, gingiva (gums), lips, palate (roof of the mouth), maxilla or mandible¹⁴. Most oral cancers look very similar under the microscope and are called squamous cell carcinoma¹⁵. These are malignant and tend to spread rapidly. These oral cancers are heterogeneous and arise from different parts of the oral cavity, and having different predisposing factors like tobacco, viral disease, unhygienic oral cavity, uv rays exposure, denture problems leads irritation of buccal mucosa etc¹⁶.

Anatomy of oral cavity

The oral cavity include the the major portion oral cavity proper and small portion known vestibule, the lip was a fleshy fold belong the mucocutaneous junction externally skin and internally mucosa membrane. The cheek is the larger part fleshy part on each side of face consist of superficial fascia some facial muscles, glands and ducts. In total oral cavity proper antrolaterally the teeth, gums and alveolar arches of jaw. The roof is formed by soft palate and hard palate, the floor is tongue and sublingual region. The oral cavity posteriorly communicates with pharynx¹⁷.

Anatomy of oral cavity

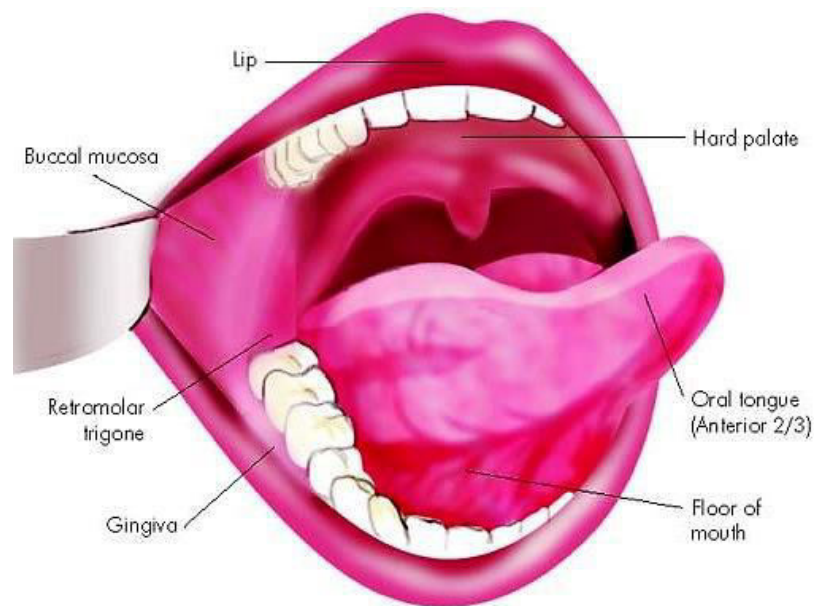


Figure -3

Lymphatic drainage of oral cavity

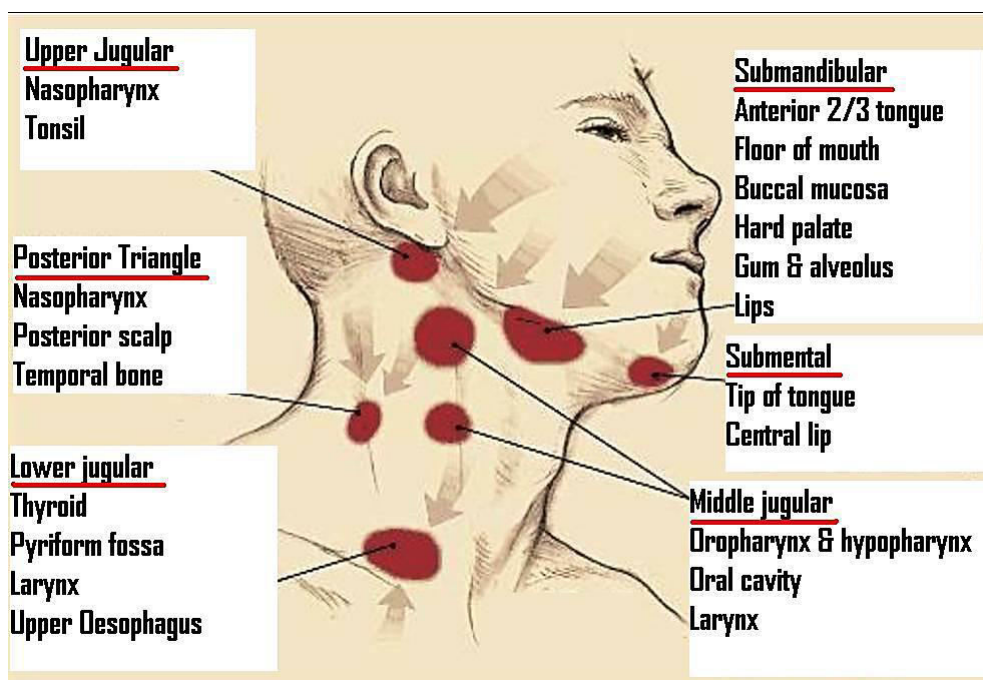


Figure-4

Risk factors for oral cancer

The risk factors tobacco which may play a synergistic role in oral cancer. From relative risk factors of alcohol and tobacco, it has been estimated, that 75% of all oral cancers¹⁸. In the remaining 25% of patients who are not exposed to these tobacco and tobacco containing substances and alcohol, the cause of their tumors remains others. The disproportionately higher incidence of carcinoma of the head-neck in relation to other malignancies in India, may be due to use of tobacco in various forms, consumption of alcohol, low socioeconomic condition related to poor hygiene, poor diet and viral infections.

Tobacco

Oral neoplasia has been associated with chewing of tobacco with betel quid (BQ) in India and other asian countries, smoking of various forms of tobacco (e.g., bidis, pipes, cigars and cigarettes) is carcinogenic in humans¹⁹. Chewing of tobacco with BQ increases exposure to carcinogenic tobacco-specific nitrosamines (TSNA) and to nitrosamines derived from areca nut alkaloids. Furthermore, reactive oxygen species (ROS) implicated in multistage carcinogenesis, are also generated in substantial amounts in the oral cavity during chewing²⁰.

Betel Quid and Areca Nut

Betel chewing is the most important etiological factor in oral carcinomas. The use of betel quid, containing both areca nut and tobacco, is associated with a much higher risk of oral cancer, BQ chewing produces ROS that is directly involved in tumor initiation process, by inducing mutation, or by making the mucosa susceptible

to BQ ingredients. alkaline during the auto oxidation of areca nut (AN) poly phenols, in the BQ chewer's saliva²¹. The ROS can be directly involved in the tumour initiation process, by inducing gene mutation leading to structural change in the oral mucosa, that may facilitate the penetration by other BQ ingredients and environmental toxicants. The AN-specific nitrosamines occurs in the saliva of BQ chewers. These AN-specific nitrosamines are mutagenic, genotoxic and capable of inducing tumours in animal models²².

Alcohol

Alcohol cause both independently also along with smoking cause in oral carcinogenesis. alcohol may act as a solvent for the penetration of carcinogens into target tissues. Acetaldehyde, which is the alcohol metabolite, has been identified recently as a tumor promoter²³.

Viruses

Human papilloma virus (HPV), which is also closely associated with benign and malignant type oral lesions. This virus identified in condylomas, cell hyperplasia of oral cavity, squamous cell papilloma and malignant oral lesions. HPV positivity is higher in tumors from the oral cavity (59%), pharynx (43%) and larynx (33%). studies indicate that tumorigenic conversion of human papilloma virus requires the presence of other risk factors²⁴.

Diet

The importance of diet and nutrition in oral neoplasia has been too much important but some features also lead to malignant changes, even more than that many foods help to prevent cancer changes of oral cavity. Fruits and vegetables (high in vitamins A and C) are protective in oral neoplasia, fruits and vegetables rich in beta-carotene, vitamin C and vitamin E, with anti-oxidant properties help to prevent cancer. Whereas meat and red chili powder are thought to be risk factors²³. Iron deficiency, is associated with cancer of upper air and food passages and dietary iron may play a protective role in maintaining the thickness of the epithelium.

Family History of Head and Neck Squamous Cell Carcinoma (HNSCC)

A family history of head and neck cancer is a risk factor also. The ability to repair DNA damaged by tobacco carcinogens, such as benzo-[a]-pyrene diol epoxide, is defective in some patients with head and neck cancer. Head and neck cancer patients show an increased susceptibility to chromosome damage by mutagens.

Immune Deficiency

A defective immune response, the Human Herpes virus type 8 (HHV-8) and Epstein-Barr virus has been commonly associated with the immune system commonly associated with and may occur in the head and neck²⁴. Oral squamous cell carcinomas of the lip are more common in transplant recipients receiving immunosuppressive therapy, but HIV infection does not predispose to intra-oral squamous cell carcinoma.

Candida

Candida albicans can induce epithelial proliferation and can produce carcinogens. Chronic hyperplastic candidosis presents as nodular or speckled-white mucosal plaques. They are potentially malignant oral epithelial lesions.

Pathogenesis

All tumour both benign and malignant have two basic components, a parenchyma and a supportive stroma²⁵ OSCC is a result of multiple genes alterations, which are modulated by individual predisposing conditions and environmental influences. Furthermore, in the last ten years a new category of non-genetic events able to modify gene expression has been massively investigated: the so called 'epigenetic'²⁶ Epigenetic factors are non-genetic phenomena which interfere with genes expression. Such modifications pass on successive generations of cells, even if there is no mutation in corresponding genes. Epigenetic events are linked with carcinogenesis when one or more oncogenes/tumour suppressors are directly or indirectly affected such that their expression and function may be permanently altered phenomena²⁷, Cellular aging, risk factors and, as recently discovered, chronic inflammation via mediators, such as IL-6, may be potential inducers of epigenetic alterations in oral mucosa cells. It is a general belief that these alterations would accumulate in the normal-appearing mucosa while carcinogenesis is in progress, or before any tumor lesion is detected.

Aethio-pathogenesis

- DNA damage
- Mucosal stem cells (in the basal layer) self-renew and also generate daughter cells that divide more rapidly (parabasal layers) and undergo maturity to terminal differentiation
- Mucosal stem cells and their daughter cells undergo continuous assault from carcinogens (e.g. tobacco) and oncogenic viruses (e.g. HPV) which cause DNA damage (also spontaneous). Damaged DNA in mucosal stem cells may be repaired by the cell or may remain to be maintained in the self-renewal process and transmitted to daughter cells
- Genetically damaged daughter cells and stem cells are continuously exposed to new carcinogens (e.g. cigarette smoke) and co-carcinogens (e.g. alcohol) & can eventually be transformed into a malignant cell undergoing uncontrolled division (Multiple hit theory of carcinogenesis)
- Five events in humans are required to transform a normal cell to a cancer cell
- The genetic alterations: tumor suppressor gene inactivated by mutation (eg p53) or oncogene activated by mutation or amplification

Sequence of changes

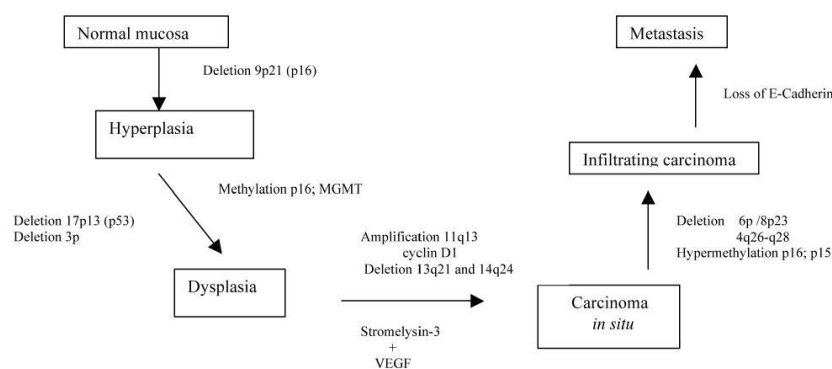


Figure-5

Carcinogenesis

Clearly the OSCC develops over many years and during this period there are several neoplasial sites transforming and taking place in the oral cavity²⁸. Oral carcinogenesis is a highly complex multifactorial process that occurs when epithelial cells are affected by various genetic alterations²⁹, including key disorders on TP53, NOTCH1 (Notch homologues are translocation-associated [Drosophila]), EGFR (epidermal growth factor receptor), CDKN2A (cyclin-dependent kinase inhibitor 2a), STAT3 (signal transducer and activator of transcription 3), Cyclin . Probably oral carcinogenesis starts with the transformation of a limited number of normal keratinocytes. This transformation can be expressed via cytogenetic changes and epigenetic processes that modify the progression of the cell cycle, DNA repair mechanisms, cell differentiation and apoptosis, which may be caused by random mutation, by exposure to a variety of biological factors, carcinogens or errors in the DNA repair process, resulting in an unstable keratinocyte into a pre-cancerization field and leading to malignant neoplastic changes, which can inherit these alterations to their clones. Subsequently, selection pressures on the microenvironment of the oral mucosa may act on the heterogeneous clonal population, allowing perpetuate those cells with better tools and advantages of adaptability, survival and proliferation above their normal neighboring cells. Tumorigenesis requires multiple essential elements: a limitless replicative potential, self-sufficiency in growth signals, lack of sensitivity to anti-growth signals, the ability to evade apoptosis, increased angiogenesis, invasion and metastasis³⁰. Recent evidence supports that the biophysical and biochemical signs of tumor-associated into the extracellular matrix influence the essential characteristics of cancer and therefore are essential for malignancy.

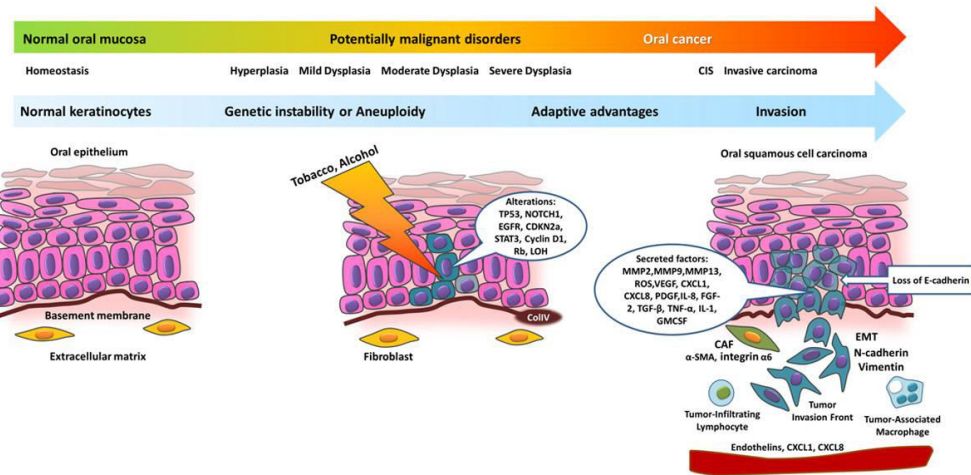


Figure -6

Tumor microenvironment (TME)

For an effective approach to cancer, it should be considered as a disease that involves complex interactions among a community of heterotypic cells, characterized by the original cancerous tissue, the newly formed tissue and cells surrounding it. The TME of OSCC include cancer-associated fibroblasts, immune cells and other supporting cells. Oncogenic changes in gene expression profiles contribute to micro environmental alterations such as ROS accumulation, overproduction of cytokines and epithelial mesenchymal transition³¹. CAFs are some of the most critical elements of TME, contributing to proliferation, invasion and metastasis. The adaptive immune response is suppressed in OSCC through overexpression of cytokines, induced OSCC

TNM staging for Oral Cancer

Primary tumor (T)

TX	Cannot be assessed
T0	No evidence of primary tumor
Tis	Carcinoma in situ
T1	Tumor 2 cm or less in greatest dimension
T2	Tumor more than 2 cm but not more than 4 cm in greatest dimension
T3	Tumor more than 4 cm in greatest dimension
T4a	Moderately advanced local disease. Lip: Tumor invades through cortical bone, inferior alveolar nerve, floor of mouth, or skin (chin or nose). Oral cavity: Tumor invades through cortical bone, into deep/extrinsic muscle of tongue (genioglossus, hyoglossus, palatoglossus, and styloglossus), maxillary sinus, or skin of face.
T4b	Very advanced local disease. Lip and oral cavity: Tumor invades masticator space, pterygoid plates, or skull base; or encases internal carotid artery

Regional lymph nodes (N)

NX	Cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in a single ipsi lateral lymph node, 3 cm or less in greatest dimension

N2	Metastasis as specified in N2a, 2b, 2c
N2a	Metastasis in a single ipsilateral lymph node, more than 3 cm but not more than 6 cm in greatest dimension
N2b	Metastasis in multiple ipsilateral lymph nodes, none more than 6 cm in greatest dimension
N2c	Metastasis in bilateral or contralateral lymph nodes, none more than 6 cm in greatest dimension
N3	Metastasis in a lymph node more than 6 cm in greatest dimension

Distant metastasis (M)

MX	Distant metastasis cannot be assessed
M0	No distant metastasis

Clinical stages (T+N+M)

0	Tis	N0	M0
I	T1	N0	M0
II	T2	N0	M0
III	T3 , T2 or T1	N1	M0
IV A	T4a	N0 or N1	M0
	T1, T2 or T3	N2	M0
IV B	any T	N3	M0
	T4b	any N	M0
IV C	any T	any N	M1 ³²

Diagnostic testes

Brush biopsy or exfoliative cytology

Incisional biopsy

Fine needle aspiration biopsy

Mucosal staining

Chemiluminescent light

Imaging testes CT, CAT, PET, MRI, BARRIUM SWALLOW

ICD classification

C 00- Malignant neoplasm of lip

C 01- Malignant neoplasm of base of tongue

C 02- Malignant neoplasm of other unspecified part of tongue

C 03- Malignant neoplasm of gum

C 04- Malignant neoplasm of floor of mouth

C 05- Malignant neoplasm of palate

C 06- Malignant neoplasm of other and unspecified parts of mouth³³

Psychological aspects

The word "cancer" is enough to put the strongest person in despair. The effect of the word on the personality of the person starts right from the time a biopsy is demanded for the diagnosis; with heightened anxiety till the reports arrive. Once the patient is confirmed to have oral cancer or even for that matter pre-malignant lesion the psychological support is needed. The deleterious effect of oral cancer on the

psychosocial well being of the patient is one of the major challenges. Also, if the cancer is treated once, the fear of recurrence or relapse curtails the person's happiness and confidence. The effect of cancer surgery that leads to the disfigurement of face, changes the complete insignnia of the person. The functions of taste, expression of feelings, speech and its contribution to aesthetics, to a large extent, make the oral cavity a unique organ. Oral cancer poses not only to the health of oral cavity, but to overall health. The increasing morbidity and mortality associated with this oral disease has made the health of oral cavity a cause of great concern

Quality of life

Health-related quality of life (QoL) has been extensively used in oral cancer survivors to identify the impact of the treatment-related morbidity and physical issues. This is used for newly diagnosed ang treatment going cases also recurrence of disease. In oral cancer patients poor oral and physical health-related QoL are found compared with the normal people.QLQ-C30 is a questionnaire commonly use to evaluate the general quality of life of cancer patients. The QLQ-H&N35 is one of the disease-specific for head and neck cancer. The EORTC QLQ-H&N35 contains 43 questions and is divided into six symptom pain, swallowing, senses (taste/smell), speech, social eating, and social contact, and seven single items impaired sexuality, teeth problems, mouth opening, dry mouth, sticky saliva, coughing, and feeling ill³⁴. Every scale is transformed into a score ranging from 0 to 172. In contrast, a higher score on the symptom scale or single item scale reflects a worse symptom or problem.³⁵

Management:

Disease at the primary site or in the neck. Up to 20% of patients with controlled local disease will subsequently develop further primary carcinomas in the upper aero digestive tract. Death owing to distant metastases, once considered to be a rare feature, is now more common as a result of better locoregional control³⁶. However, even if local disease control is better it is still too early to say whether the survival figures will eventually improve. There is little evidence to date that cure rates have increased over the past four decades, although the changing pattern of disease, with a decrease in lip cancer and a rise in tongue cancer, for example, may actually mask a relative improvement in outcome.

- A) Homeopathic management: Homoeopathy is a system of medicine which has an holistic approach towards the patient. It can work fast. Unlike the modern medications the effect won't wear off after a certain period of time. And once the remedy is selected and administered in a minimum dose it is sufficient to take care of the pain and other symptoms.^[25]

According to Ronald D. Whitmont *et al* Homoeopathic pain management can be a time intensive procedure on the part of practitioner because it requires individualization of the prescription based upon the unique feature of the individual patient. It does not tend to lend itself simple "cookbook" strategies and algorithms. When properly carried out it offers maximal clinical utility and long term benefits since it often work beyond simple pain management and positively affect the clinical outcome of many disorders, which are the source of the pain³⁷.

Homoeopathic approach: Aphorism §171 to 186 - Organon of medicine.

LOCAL DISEASES- According to Hahnemann local diseases are those which are related to chronic disease arising from psora need so remedies in succession. in some disease having one few symptoms in one sided administer the partially similar anti psoric remedy^{38]}

In Homoeopathy have enormous scope in cancer have safe curative treatment in primary and secondary stage of diseases. in other stages we can control the dreadful features of disease it's a dependable alternative treatment.

The role and efficacy of homeopathic medicines for treatment of malignant tumors is largely unknown and unproven so far. Homeopathic therapy is mainly used for supportive cancer care and some have suggested an integration of this therapy with conventional methods. However, in numerous studies, it has been found that orthodox medicine is not meeting the needs of some patients and that Complementary and Alternative Medicine may wholly or partly substitute for conventional medicines. Most patients indicate that their problems improve

Homoeopathic medicines:

- 1. Calendulaofficinalis**,in In all cases of loss of soft parts when union cannot be affected. External wounds with or without loss of substance, torn and jagged looking wounds, post surgical operations, to promote healthy granulation and prevent excessive suppuration and disfiguring scars. Traumatic and idiopathic neuroma. Exhausted from loss of blood and excessive pain. It is almost specific for clean, surgical cuts or lacerated wounds to prevent excessive suppuration.³⁹
- 2. Magnesiaphosphorica**, which is often referred to as the “homeopathic aspirin.”⁴⁰ things. Pains are sharp, cutting, stabbing, shooting, stitching, lightning like in coming and going.
- 3. Silicea**,After dental surgery Silica 6 twice daily is useful to help root fragments or splinters of bone exfoliate. Has a wonderful control over the suppurative process of soft tissue, periosteum or bone.
- 4. Borax**, Aphthous ulceration of mucous membranes Aphthae. White fungous like growth. Mouth hot and tender; ulcers bleed on touch and eating. Painful gumboil. Taste bitter. Taste of "cellar mould"
- 5. Calcarea fluorica**, Powerful remedy for hard, stony glands, varicose and enlarged veins, and malnutrition of bones. manifesting itself in ulceration of mouth and throat, caries and necrosis with boring pain and heat in parts Gum-boil, with hard swelling on the jaw. Cracked appearance of the tongue, with or without pain. Induration of the tongue, hardening after inflammation. Unnatural looseness of the teeth, with or without pain; teeth become loose in their sockets. Hard swelling on the cheek.

6. **Hydrastis Canadensis**, Affinity for all mucous membrane Intense yellow color of all discharges Large, flabby, coated tongue indented by teeth; putrid taste. Peppery taste. Tongue white, swollen, large, flabby, slimy; shows imprint of teeth; as if scalded; stomatitis. Ulceration of tongue, fissures toward the edges. Cancer and cancerous state, before ulceration, when pain is principal symptom.
7. **Lachesis**, Thin and emaciated than to fleshy persons; those who have been changed, both physically and mentally by their illness Left sided affinity – diseases started on the left and go to the right side Great sensitive to touch. All the symptoms, esp. the mental worse after sleep, or the aggravation wakes him from sleep. Gums swollen, spongy, bleed. Tongue swollen, burns, trembles, red, dry and cracked at tip, catches on teeth. Aphthous and denuded spots with burning and rawness. Nauseous taste. Teeth ache, pain extends to ears. Pain in facial bones.
8. **Muriaticum acidum**, Extreme debility, constantly sliding down in bed; jaw hangs down Buccal cavity studded with numerous ulcers which have a black base and a tendency towards perforation. Tongue dry, shrunken, leather like and paralysed Irritable and peevish; fretful Loud moaning. Great restlessness. Sad, taciturn; suffers in silence. Tongue, pale, swollen, dry, leathery, paralyzed. Deep ulcers on tongue. Hard lumps in tongue. Epithelioma; edges bluish-red. Aphthous mouth. Gums and glands swollen. Fetid Breath. Sordes on teeth.

9. Mercurius solubilis, Light haired persons; skin and muscle lax Hurried and rapid talking. In bone diseases , pains worse at night; glandular swelling with or without suppurations Sweetish metallic taste. salivary secretions greatly increased; bloody and viscid. Saliva fetid, coppery. Speech difficult on account of trembling tongue. Gums spongy, recede, bleed easily. Sore pain on touch and from chewing. Whole mouth moist. Crown of teeth decay. Teeth loose, feel tender and elongated. Furrow in upper surface of tongue lengthwise. Tongue heavy, thick; moist coating; yellow, flabby, teeth-intended, feels as if burnt, with ulcers, Fetid odor from mouth, can smell it all over room. Alveolar abscess, worse at night. Great thirst, with moist mouth.

10. Nitricum acidum, Suited to thin persons of rigid fibre, dark complexion, black hair and eyes. Excessive weakness of mind and body, least exertion tires form Flat, suppurating ulcerations, irregular shape and zigzag edges; least touch causes bleeding. Putrid breath. Salivation. Bleeding of gums. Painful pimples on the sides of the tongue. Tongue clean, red and wet with center furrow. Teeth become loose; gums soft and spongy. Ulcers in soft palate, with sharp, splinter-like pains. Salivation and fetor oris. Bloody saliva.

11. Arsenicum album, White oxide of arsenic. Disposition to depressing, melancholic, despairing, indifferent Anxious, fearful, restless, anguish Irritable, sensitive, peevish, easily vexed, Mentally restless but physically too weak to move. Great prostration, burning pains. Mouth Unhealthy ,easily bleeding gums, ulceration of mouth with dryness and burning heat. Epithelioma of lips. Tongue dry, clean, ad red; stitching and burning pain

in tongue. Ulcerated with blue color. Bloody saliva. Neuralgia of teeth; feel long and very sore; worse after midnight; better warmth. Metallic taste, Gulping up of burning water. Swollen, edematous, constricted, burning, unable to swallow.

12. Kalium muriaticum, Catarrhal affections and sub acute inflammatory stages giving rise to sticky fibrinous exudations It certainly is of great value in catarrhal affections, in sub-acute inflammatory states, fibrinous exudations, and glandular swellings. white or gray coating of base of tongue, and expectoration of thick, white phlegm, seem to be special guiding symptoms. Aphthae; thrush; white ulcers in mouth. Swollen glands about jaw and neck. Coating of tongue grayish-white, dryish, or slimy.

13. Thuja, Tree of life, It is a Sycotic. Adapted to hydrogenous constitution Lymphatic temperament, very persons, dark complexion, black hair, unhealthy. Skin. Rapid exhaustion and emaciation. Tip of tongue very painful. White blisters on side close to root, painfully sore. Teeth decay next to gums; very sensitive, gums retract. Ranula; varicose veins on tongue and mouth. Pyorrhoea alveolaris

14. Syphilinum, Terrible dread of night on account of mental and physical exhaustion on awakening. Pain from darkness to daylight. All symptoms are worse at night. Teeth decay at gum; edges serrated, dwarfed. Tongue coated, teeth-indented; deep longitudinal cracks. Ulcers smart and burn. Excessive flow of saliva; it runs out of mouth when sleeping.

15. Mercurius corrosivus, Diseases of men, syphilitic; ulcers, with corroding, acrid pus, brights diseases, Face Swollen. Red, puffy. Lips black, swollen. Sordes. Facial neuralgia within the bones. Teeth loose. Gums purple, swollen, and spongy. Tongue swollen and inflamed. Salivation. Pyorrhoea. Taste salty and bitter.

Conventional management

Oral cancer is predominantly a local disease that tends to infiltrate adjacent bone and soft tissues and spreads to the regional lymph nodes in the neck. Distant metastasis is uncommon at the time of diagnosis. A thorough inspection and palpation of the oral cavity and examination of the neck is necessary for identifying and manage the case⁴¹. CT and MRI like imaging techniques are widely used to assess the extent of involvement of adjacent structures, such as bones and soft tissues. Surgery and radiotherapy are the main treatment modalities for oral cancer⁴².

Treatment of Early-Stage Oral Cancer (Stages I and II)

Surgery and radiotherapy are widely used for the treatment of early oral cancer, either as single or in combination form. The choice depends on the location of the tumor, cosmetic and functional outcomes, age of the patient, associated illnesses. Most early-stage oral cancers can be locally excised or treated with radiotherapy, .

Treatment of Locally Advanced Tumors of the Oral Cavity (Stages III and IVA)

Locally advanced tumors are aggressive, and loco-regional treatment failure rates are high. Combined modality approach integrating surgery, radiotherapy with or without chemotherapy, planned and executed by a multidisciplinary team is always preferred. medically unfit for surgery, or who are likely to have unacceptable

functional and cosmetic outcomes with surgery. Incorporating chemotherapy with surgery or radiotherapy is useful in younger patients with good general conditions increasing survival by about 5 percentage points.

Side Effects of Radiotherapy

Side effects may occur during or immediately following radiotherapy acute reactions or months to years after treatment. Acute reactions are common and generally subside within two to three weeks. These reactions are due to the inflammation of tissues within the radiotherapy treatment. Alteration of taste, pain, difficulty in eating, mucosal ulceration of the oral cavity, bacterial and fungal infections, increased thickness of saliva, discoloration of the overlying skin and desquamation, and edema of the skin are the major side effects.

Complications of Surgery

The common complications of surgery are infection, skin necrosis, flap failure, and wound breakdown. Resorption of bone, osteomyelitis, and salivary fistula can also occur. It can cause cosmetic appearance and functions such as speech, swallowing, and Airway defects.

4.0 MATERIALS AND METHODS

4.1 STUDY SETTING:

This study is designed to evaluate the Homoeopathic medicine in treatment of oral cancer in the way, its efficacy to improving the quality of Life (QoL) in oral cancer patients. The study will be carried out at Out Patient Department (OPD).and In Patient Department (IPD) and peripheral centers of Sarada Krishna homoeopathic medical college.

4.2SELECTION OF SAMPLES:

Sample Size: . To be based on disease prevalence

Sampling Technique: Random sampling.

4.3METHODOLOGY:

Total sample patients were selected from the Out Patient Department and In Patient Department and peripheral centers of Sarada Krishna Homoeopathic Medical College whose suffer from oral malignancies or suspected to suffer from oral malignancies .The patient pre assessment and post assessment were done with Quality of life scale.

OBSERVATION AND FOLLOWUP:

Then from the diagnosed cases of oral cancer by clinical examination and investigation coming to our OP, Ip and peripheral centers from screened peoples

details were collected in pre-structured case format and determine the stage of disease. Life standards were assessed by Quality of life scale. Then details were analyzed for making the totality, Then the totality was repertorized to select a most suitable remedy with the guidance of Homoeopathic Materia medica and administered to patients who gave valid consent and study the efficacy for improving the Quality of Life.

The follow up were done once in every months for six months and changes were recorded and every changes was assessed with by QoL scale. The changes was recorded and analyzed statistically.

INTERVENTION:

- Case taking
- Comparing pre and post assessment, the study was be intervened.

Pre-assessment: Baseline intensity of Quality of life in study subject.

Post-assessment: Changes from the baseline intensity of Quality of Life in study subjects.

SELECTION OF TOOLS:

- Pre structured case format.
- Quality of life scale QLS
- Repertory – RADAR- Synthesis 9.1.
- Homoeopathic remedies for oral cancer.

4.4 INCLUSION CRITERIA:

- Both the genders.
- Patients above 18 years of age.

- Person who suffering from oral cancer or suspected to cancer.

4.5 EXCLUSION CRITERIA:

- Patients who are unwilling to take Homoeopathic treatment.
- Patient under allopathic treatment.
- Patient who were in necessary need for any emergency surgery radio or chemo therapy for survival.

4.6 OUTCOME ASSESSMENT:

OUTCOME ASSESSMENT:

To assess the effectiveness of Homoeopathic medicines in improving the Quality of life by QoL scale.

Patients were assessed as follows.

- Marked Improvement: Complete relief of pain and symptoms.
- Moderate improvement : Slight relief of pain and few symptoms.
- Mild improvement: Very slight relief in disease condition.
- No improvement : No relief in symptoms.

Dropped out: Cases which were left out during study period.

4.7 STATISTICAL TECHNIQUES & DETAILS ANALYSIS:

Pre-test and post-test assessments were done. Hypothesis was analyzed by paired “t” test. Both paired and unpaired was used to compare between the groups. Details are represented in charts and graphs.

5.0 OBSERVATIONS AND RESULTS

A sample of thirty cases from the patients who attended the cancer pain and palliative care OPD , Peripheral Health centers (Kovalam and Colachal), of Sarada Krishna Homoeopathic Medical College and Hospital was taken for this study. From the data obtained,the results are presented in the following tables.

5.1 DISTRIBUTION OF CASES ACCORDING TO AGE

S.No.	Age groups	No. of cases	Percentage
1	35-45 years	2	6.66%
2	46-55 years	5	16.67%
3	56-65 years	11	36.67%
4	66-75 years	6	20%
5	76-85 years	6	20%

Table No. 1

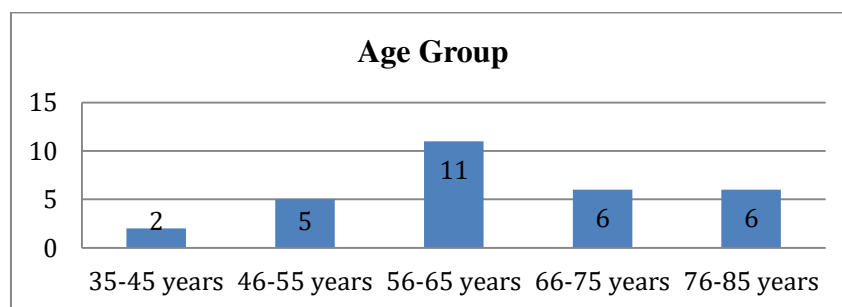


Figure-7

Findings:The age group of the sample varies from 35 – 85 years. Among this the maximum number of 11 patients is noted in age group between 56-65 years age group(36.67%).The next higher frequency is noted in 66-75 &76-85 years group with a frequency of 6patients(20%).The minimum number of patients is noted in 35-45 years group in which only 2(6.66%) patients are present.

5.2 DISTRIBUTION OF CASES ACCORDING TO SEX

S.No.	Sex	No. of cases	Percentage
1	Male	24	80%
2	Female	6	20%
3	Total	100	100%

Table No. 2

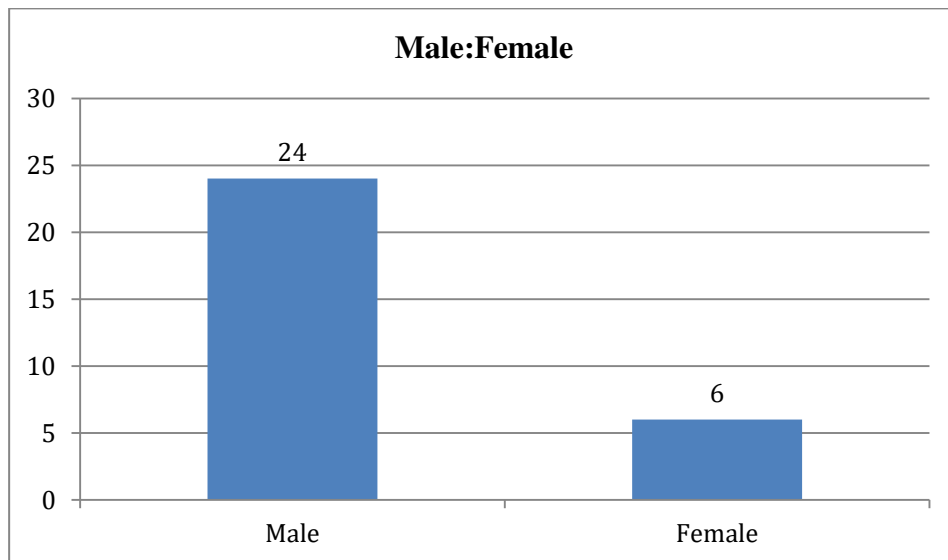


Figure No. 8

Findings: Out of the 30 patients studied 24 patients were males with a percentage of 80% and 6 patients were females with percentage of 20%.

**5.3 DISTRIBUTION OF CASES ACCORDING TO THE HOMOEOPATHIC
REMEDY GIVEN**

S.NO	MEDICINES	NO: OF CASES	PERCENTAGE
1	Nitricum acidicum	5	16.67%
2	Arsenicum Album	4	13.34%
3	Natrium muriaticum	4	13.34%
4	Thuja	3	10%
5	Lachesis	2	6.67%
6	Kali cynatum	2	6.67%
7	Opium	2	6.67%
8	Aceticum acidicum	1	3.33%
9	Calcarea carbonica	1	3.33%
10	Conium maculatum	1	3.33%
11	Hydrastis	1	3.33%
12	Kali muriaticum	1	3.33%
13	Lycopodium clavatum	1	3.33%
14	Mercurius solubilus	1	3.33%
15	Phosphorus	1	3.33%
16	Total	30	100%

Table No. 3

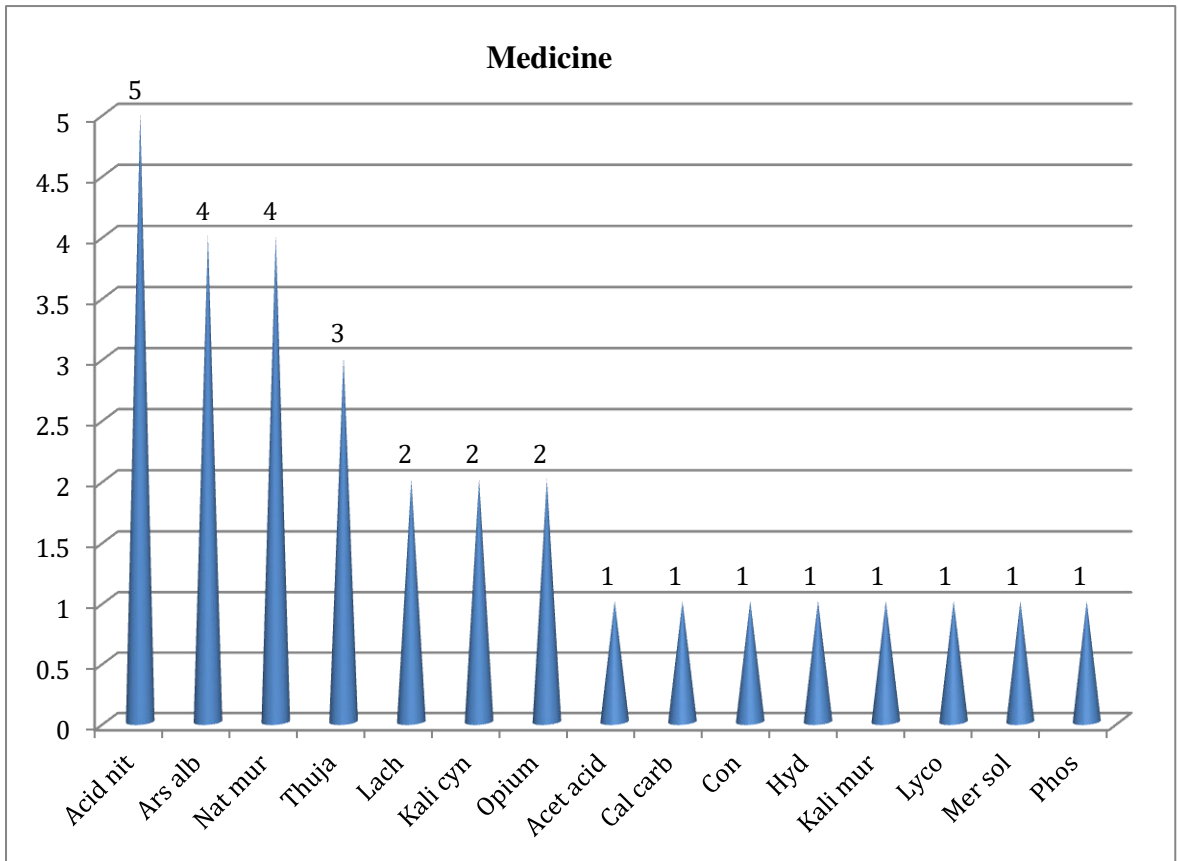


Figure No. 9

Findings: Among the 30 cases studied in , Acidicum nitricum was given to 5 cases(16.67%), followed by Arsenicum album & Natrium muriaticum for 4 cases (13.34%),Thuja indicated for 3 cases(10%), Lachesis,opium & Kali cynatum are for 2cases(6.67%) other drugs Acetic acid, Calcariacarbonicum, Conium maculatum, Hydrastis, Kalium muriaticum, Lycopodium, Mercurius solubilis, phosphorus are indicated each cases.

5.4 DISTRIBUTION OF CASES ACCORDING TO THE POTENCY GIVEN

S.NO.	TYPE POTENCY	NO: OF CASES	PERCENTAGE
1	30	7	23.333%
2	200	6	20%
3	1M	1	3.333%
4	10M	1	3.333%
5	50 Millesimal	15	50%
6	Total	30	100%

Table No. 4

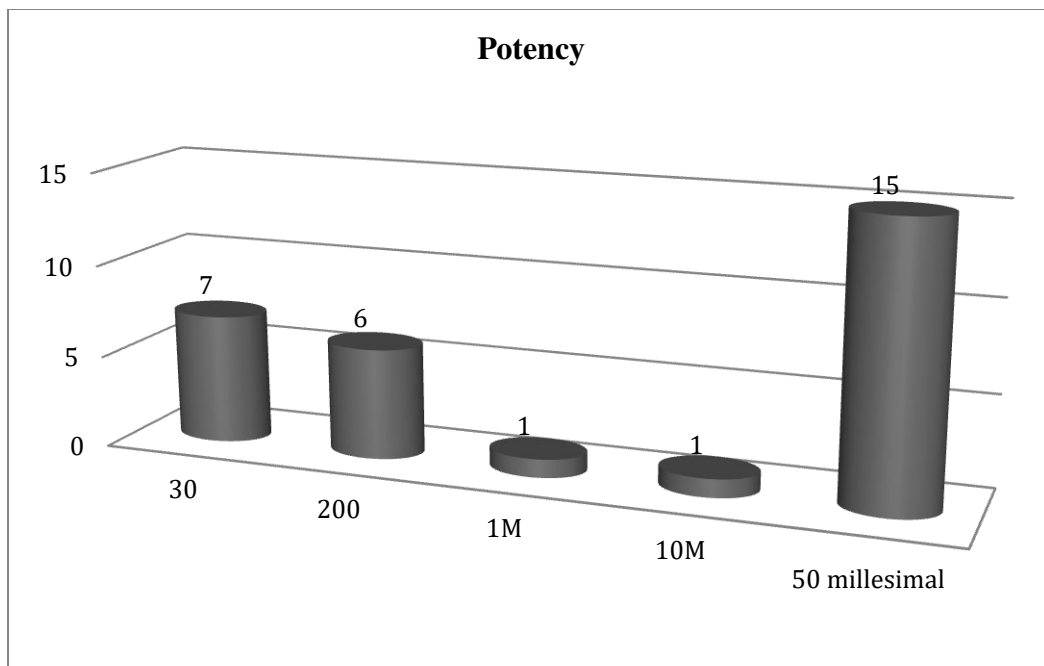


Figure No. 10

Findings; Among the 30 cases 50% of cases given 50 millesimal scale especially for frequent repetition 23.33% cases are indicted 30c potency and 20% cases are 200c potency. 3.33% present cases only indicated both 1M and 10M potencies.

5.5 DISTRIBUTION OF CASES ACCORDING TO DIAGNOSIS

S.NO.	DIAGNOSIS	NO. OF PATIENTS	PERCENTAGE
1	CA Cheek	12	40%
2	CA Tongue	7	23.35%
3	CA Oro Pharynx	3	10%
4	CA Glottis	2	6.67%
5	CA Lip	1	3.33%
6	CA Soft palate	1	3.33%
7	CA Parotid Gland	1	3.33%
8	CA Tonsils	1	3.33%
9	CA Hypo pharynx	1	3.33%
10	Leukoplakia	1	3.33%
11	Total	30	100%

Table No. 5

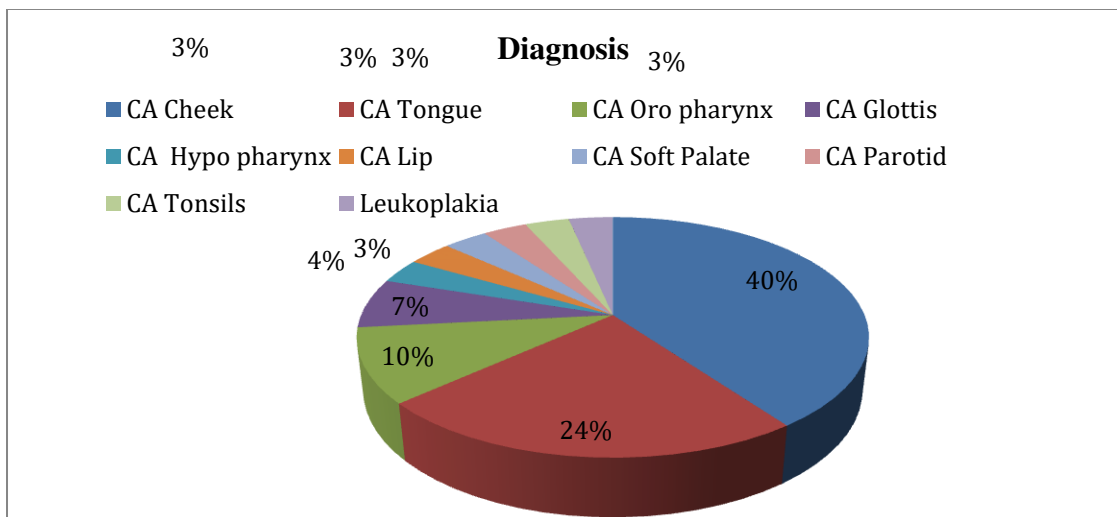


Figure No. 11

Findings: Out of the 30 cases studied, cancer of cheek was the common diagnosis seen in 12 patients(40%), followed by carcinoma of tongue in 7 patients(23.35%), Oro pharyngeal carcinoma found in 3 patients(10%) and CA glottis in 2 patients (6.67%) each.one case was found in Carcinoma of lip, Soft palate, Hypopharynx, Parotid Gland, Tonsils and Leukoplakia.

5.6 DISTRIBUTION OF CASES ACCORDING TO IMPROVEMENT

S.NO.	IMPROVEMENT	NO. OF PATIENTS	PERCENTAGE
1	Marked improvement	8	26.67%
2	Moderate improvement	6	20%
3	Mild improvement	11	36.67%
4	Not significant improvement	1	3.33%
5	No change	4	13.33%
6	Aggravation	0	0%
7	Total	30	100%

Table No. 6

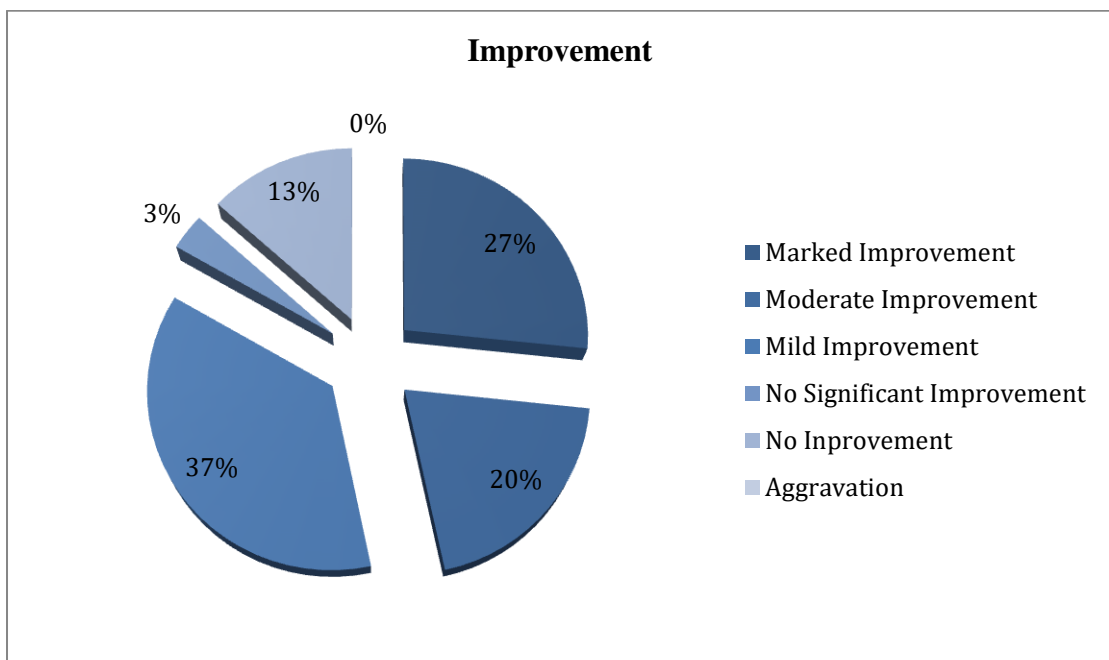


Figure No. 12

Findings: According to the improvement of quality of life after treatment, the study population is categorised under the headings Aggravation (0%), No change and discontinued (13.33%), Not significant improvement(3.33%), Mild improvement(36.67%), Moderate improvement(20%), Marked improvement(26.67%)Out of 30 cases.

5.9 COMPARISON OF OLQ SCORING BEFORE AND AFTER

S.NO.	BEFORE	AFTER
1	119	90
2	138	121
3	143	142
4	131	117
5	117	68
6	119	78
7	136	102
8	109	82
9	143	142
10	123	115
11	101	98
12	121	108
13	114	102
14	94	88
15	125	95
16	130	122
17	111	81
18	115	114
19	139	94
20	143	123
21	155	131
22	124	113
23	143	120
24	121	108
25	96	65
26	115	104
27	100	77
28	138	120
29	146	98
30	128	127

Table No. 7

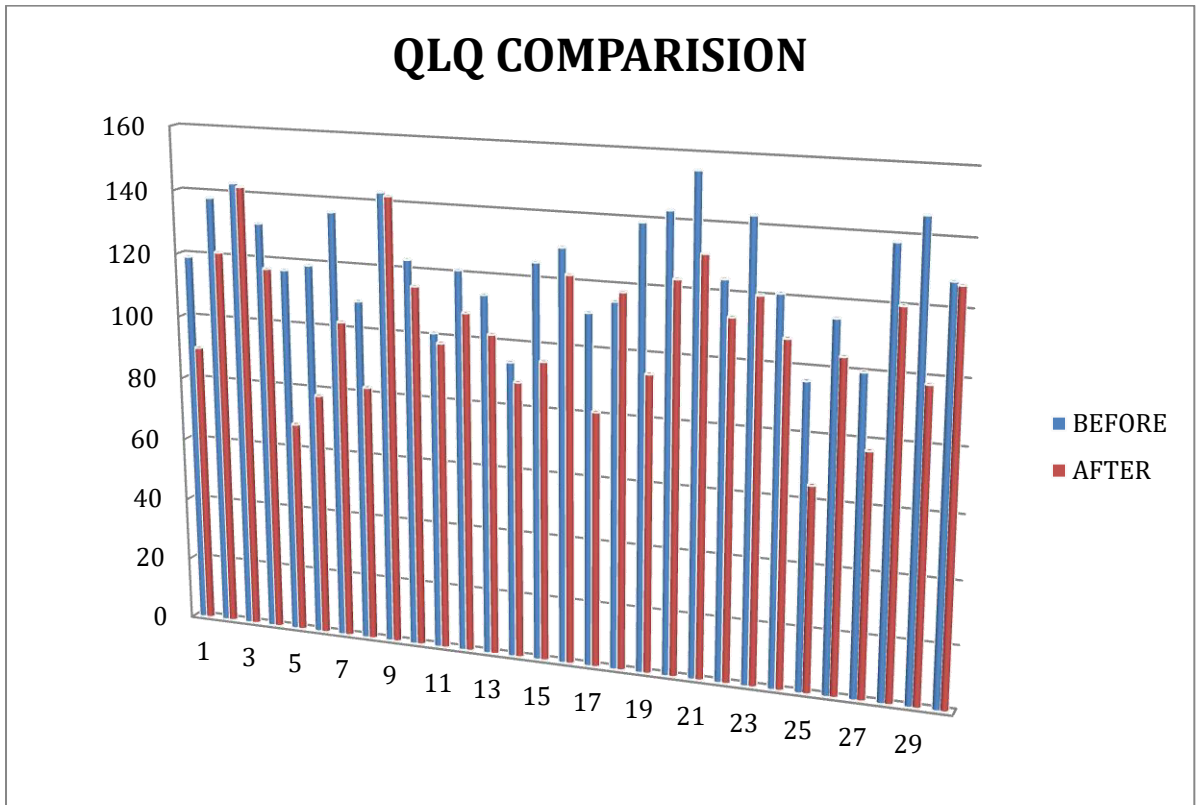


Figure No.13

Findings: Further I have compared the QLQ scoring of the patients before and after it is evident that eight cases showed marked changes, six with moderate changes and 11 had mild changes so can conclude eighty four percentage cases showed changes.

6.0 STATISTICAL ANALYSIS

Sl no	X	Y	D	$D - \bar{D}_1$	$(D - \bar{D}_1)^2$
1.	119	90	29	9.27	85.9329
2.	138	121	17	-2.73	7.4529
3.	143	142	1	-18.73	350.8129
4.	131	117	14	-5.73	32.8329
5.	117	68	49	19	361
6.	119	78	41	21.27	452.4129
7.	136	102	34	14.27	203.6329
8.	109	82	27	7.27	52.8529
9.	143	142	1	-18.73	350.8129
10	123	115	8	-11.73	137.5929
11	101	98	3	-16.73	279.8929
12	121	108	13	-6.73	45.2929
13	114	102	12	-7.73	59.7529
14	94	88	6	-13.73	188.5129
15	125	95	30	10.27	105.4729
16	130	122	8	-11.73	137.5929
17	111	81	30	10.27	105.4729
18	115	114	1	-18.73	350.8129
19	139	94	45	25.27	638.5729
20	143	123	20	0.27	0.0729
21	155	131	24	4.27	18.2329
22	124	113	11	-8.73	76.2129
23	143	120	23	3.27	10.6929
24	121	108	13	-6.3	39.69
25	96	65	31	11.27	127.0129
26	115	104	11	-8.73	76.2129
27	100	77	23	3.27	10.6929
28	138	120	18	-1.73	2.9929
29	146	98	48	28.27	799.1929
30	128	127	1	-18.73	350.8129
	Total		592		5458.531

X= Score before treatment

Y= Score after treatment

d₁= Difference between before and after score

Standard error of the mean differences:

The mean of the differences, $\bar{d}_1 = \Sigma d_1/n=592/30=19.73$

The estimate of population standard deviation is given by,

$$\Sigma(d_1-\bar{d}_1)^2=5458.531$$

$$SD = \sqrt{\Sigma(d_1 - \bar{d}_1)^2 / n - 1}$$

$$= \sqrt{5458.531/29}=13.71$$

$$\text{Standard error (S.E)} = S.D/\sqrt{n}$$

$$=13.71/\sqrt{30}=2.50$$

A. The test statistics is Paired t:

$$\text{Critical ratio, } t = \frac{\bar{d}}{S.D/\sqrt{n}}$$

$$= 19.73/ 2.50 =7.89$$

t-Test: Paired Two Sample for Means

	<i>Variable</i> <i>1</i>	<i>Variable</i> <i>2</i>
<i>Mean</i>	<i>124.5667</i>	<i>104.8333</i>
<i>Variance</i>	<i>251.9092</i>	<i>415.9368</i>
<i>Observations</i>	<i>30</i>	<i>30</i>
<i>Pearson Correlation</i>	<i>0.71415</i>	
<i>Hypothesized Mean Difference</i>	<i>0</i>	
<i>df</i>	<i>29</i>	
<i>t Stat</i>	<i>7.539487</i>	
<i>P(T<=t) one-tail</i>	<i>1.3E-08</i>	
<i>t Critical one-tail</i>	<i>1.699127</i>	
<i>P(T<=t) two-tail</i>	<i>2.6E-08</i>	
<i>t Critical two-tail</i>	<i>2.04523</i>	

E. Comparison with tabled value:

This critical ratio, t follows a distribution with n-1 degrees of freedom. The 5% level is 2.045 and 1% level is 2.756 for 29 degrees of freedom. Since the calculated value 7.53 is greater than tabled value at 5% and 1% level, the test is statistically significant and hence the null hypothesis is rejected.

F. Inference:

This study shows significant reduction in the disease intensity scores after giving homoeopathic medicines for Efficacy of improving the quality of life in oral cancer.

7.0 DISCUSSION

The study was conducted on the patients with oral cancer from the Out Patient Department, In Patient Department and peripheral health centers of Sarada Krishna Homoeopathic Medical College Hospital, to study the efficacy of Homoeopathic medicine for improving the life quality. The quality of life was accessed using the quality of life scale.

A total of 30 cases were selected as per the inclusion criteria and details of cases were recorded in standardized chronic case record. Patients above the age group of 18years were selected. The cases were diagnosed based on clinical presentation and investigation results and previous treatment reports. The patients and symptoms were analysed and the medicine was prescribed based on erected totality . The cases were analyzed using quality of life questioner before treatment started which is specific for cancer on head and neck. Then the totality based indicated medicine was administered . The cases were followed for monthly min for six month clinical assessment of quality of life before and after treatment, based on EORTC quality of life questioner for H&N43 scoring which marks during follow up. Then paired 't' test was applied and for the comparison of efficacy of homoeopathic medicine in improving the life quality of oral cancer patient before and after treatment.

Based on the analysis from 30 cases of oral carcinomas which I have included in my study, following observations are made.

AGE: Out of 30 cases, most number of patients were in the age group of 56- 65years which was 11 patients is seen in the 56-65 years age group(36.67%).The next higher frequency is seen in 66-75 &76-85 years group with a frequency of 6patients(20%).The minimum number of patients is seen in 35-45 years group in which only 2(6.66)This corresponds to the older studies according to which the major part of carcinoma take place above 40 years of age. From this it is evident that oral carcinomas are more common in fifth decade of life.

SEX:In this study its found that the population affected more with oral cancer were males(n=24) which corresponds to the earlier studies the men are commonly affecting with oral carcinomas and majority of having etiological factor like tobacco etc.The result almost similar to previous study of Mehrotra R, Yadav's Oral squamous cell carcinoma: Etiology, pathogenesis and prognostic value of genomic alterations.

REMEDY: From the 30 cases taken in the totality based treatment and a single medicine can't be said as most indicated medicine in oral cancer. A wide group of different medicine are indicated on individualistic basis Among the 30 cases studied in, Acidicum nitr icum was given to 5 cases(16.67%), followed by Arsenicum album & Natrium muriaticum for 4 cases (13.34%),Thuja indicated for 3 cases(10%), Lachesis, opium &Kali cynatum are for 2cases(6.67%) other drugs Acetic acid, Calcariacarbonicum, Conium maculatum, Hydrastics, Kalium muriaticum, Lycopodium, Mercurius solubilise, phosphorus are indicated each cases. From this broadly we can conclude that acid group and mineral group medicines are most effective in oral cancer.

TYPE CANCER: Out of the 30 cases studied, cancer of cheek was the common diagnosis seen in 12 patients (40%), followed by carcinoma of tongue in 7 patients (23.35%), Oro pharyngeal carcinoma found in 3 patients (10%) and CA glottis in 2 patients (6.67%) each. one case was found in Carcinoma of lip, Soft palate, Hypo pharynx, Parotid Gland, Tonsils and Leukoplakia. Its also validating the previous studies the eighty percent of oral carcinomas are squamous cell carcinomas of cheek and buccal mucosa and next to that is carcinoma of tongue.

REASON FOR CANCER: From this study it is evident that most number of oral malignancies' are having strong etiological factors. Tobacco is the prime and major causative agent of oral cancers. Out of thirty cases sixteen cases are having history of tobacco usage for years of exposure. Its also validating the previous studies says that tobacco is the major risk factor of oral cancers.

IMPROVEMENT STATUS: Among the 30 cases According to the improvement of quality of life after treatment, the study population 26.67% patient shows Marked improvement; 20% had moderate improvement; 36.67% had mild improvement. 0% had aggravation; 13.33%, Not change and discontinued, 3.33%, had no significant improvement

The study shows that the homoeopathic medicine have efficacy in oral cancer management and can improve quality of life. There show marked changes in before and after evaluation and can be helpful for even managing the early stages of disease.

Results obtained from these treatment statistically analysed using paired t test the before and after value.

This critical ratio, t follows a distribution with n-1 degrees of freedom. The 5% level is 2.045 and 1% level is 2.756 for 29 degrees of freedom. Since the calculated value 7.53 is greater than tabled value at 5% and 1% level, This study shows significant reduction in the disease intensity scores after giving homoeopathic medicines for Efficacy of improving the quality of life in oral cancer.

8.0LIMITATIONS

- Number of samples used in this study is very small. Therefore, generalisation of the result and inferences of the study need to be done cautiously.
- Selections of cases were difficult since many of the cases were irregular for reporting, some of them even dropped out and the patients
- There was no control group since the sample size was small.
- In some cases, necessary information was lacking and the study was based on the available data.
- Majority of cases in advanced stage of disease so that the result of early stage find out is a greater limitation.
- The majority cases are palliative stage

8.1 RECOMMENDATIONS

- Bigger sample size with extended time of research would provide better results.
- It was better, if control (placebo) group would have been kept simultaneously to verify the effectiveness of treatment.
- Universal standardized scale can be used, so that evaluation of outcome of the study would become precise.
- Further study has to be conducted to know the curative action of medicines.
- Inclusion criteria should include adolescence and geriatric age group to generalise the results.
- Further study has to be conducted based on specific stage of disease and specific type of cancer.

9.0 CONCLUSION

According to the study on the efficacy of homoeopathy in improving the quality of life in patients with oral cancer, the effectiveness of management and scope of homoeopathy, the following conclusions were drawn out of 30 case samples:

Majority of patients belongs to the age groups 56-65yrs (36.67%) and 66-75yrs (20%). Oral cancer is prevalent more in males than in females. The study shows that homoeopathic medicine was effective in improving the life quality of patients. Mild improvement was observed in 36.67% of the cases. Moderate improvement was observed in 20% of cases. There was marked improvement in 26.67% of cases. The Homoeopathic medicines, which were found to be more effective, include Nitric acid, Arsenicum album, Thuja and certain other acid group remedies. In most of the cases, acid and mineral group medicines were indicated, especially nitric acid ,kali cyanatum, arsenic. The most common type of oral cancer was squamous cell carcinoma of buccal mucosa and cheek. From this study we can conclude that, Homoeopathic medicines have significant effect in managing the manifestation of oral cancer and it help in improving life quality. The result of the study shows that the cases managed by homoeopathic medicines showed a steady improvement in quality of life in patients with oral cancer.

10.SUMMARY

A sample of 30 cases of oral cancer was taken randomly for the study as per the inclusion criteria and cases were managed with homoeopathic medicines. Each case was taken and totality was erected. Remedy was selected according to the totality. The patients were assessed to mark the changes before and after treatment (Quality of life scale). Follow up is assessed each month respectively or as per the need of the case for six month duration.. Cases were analysed according to the “Quality of Life scale Scoring” monthly and compare before and after treatment. To know about the effectiveness of homoeopathic medicine in improving the quality of life after treatment, paired” t “test was done. It showed that there is significant change in quality of life before and after the treatment in all of the cases. Hence it could be concluded that the quality of life of patients with oral cancer can be improved by Homoeopathy.

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APPENDIX I – GLOSSARY

1.	AGGRAVATION	The state of becoming worse or more serious.
2.	AMELIORATION	The act of making something better.
3.	REMEDY	A medicine or treatment for a disease or injury.
4.	POTENCY	The power of something to affect the mind or body; the number of times a remedy has been diluted & succussed, taken as a measure of the strength of the effect it will produce.
5.	DOSE	A quantity of medicine prescribed to be taken at one time.
6.	INFLAMMATION	Defined as the local response of living mammalian tissue to injury due to any agent.
7.	MALIGNENCY	
8.	HYPERALGESIA	Increase in perceived magnitude of a painful stimulus.
9.	TUMOR	A abnormal mass of tissue
10.	METASTASIS	Development of secondary malignant growths at a distance from a primary site
11.	QUALITY OF LIFE	Assessment of their well being or lack thereof
12.	CARCINOGENESIS	A substance or agent that cause cancer

Appendix - V

“Case records are our valuable asset”

SARADA KRISHNA

HOMOEOPATHIC MEDICAL COLLEGE & HOSPITAL

KULASEKHARAM, KANYAKUMARI DIST, TAMIL NADU- 629161

CHRONIC CASE RECORD

O.P. No:

UNIT :

Date:

Name:

Age: Sex: Religion: Nationality:

Name of father/Spouse/Guardian/Son/Daughter:

Marital status:

Occupation:

Family size:

Diet:

Address:

Phone No (Mobile):

FINAL DIAGNOSIS:

Homoeopathic	
Disease	

RESULT:	Cured	Relieved	Referred	Otherwise	Expired

2. INITIAL PRESENTATION OF ILLNESS

PATIENT'S NARRATION (in the very expressions used by him/her)	PHYSICIAN'S INTEROGATION (details Regarding symptoms narrated)	PHYSICIAN'S OBSERVATION

3. PRESENTING COMPLAINTS

LOCATION (tissues,organs,systems extensions & duration direction & frequency)	SENSATION & PATHOLOGY	MODALITY (>,<) & A/F (=)	CONCOMITANTS IF ANY

4. HISTORY OF PRESENTING ILLNESS:

5. HISTORY OF PREVIOUS ILLNESS

NO	Age/Year	Illness, trauma, fright, burns, drug allergy(ies), operation(s), exposure(s), innoculation, vaccination(s), serum, steroids, hormone therapy, antibiotics, analgesics, etc.	Treatment Adopted	Outcome

8. LIFE SPACE INVESTIGATION

9. MENSTRUAL HISTORY:

A.Menses

L.M.P:

Amenorrhoea-

Primary/Secondary

Cycle/Regularity &its Duration	Duration Of Menses	FLOW			
		Qty	Consistency &clots	Color & ododr	Stains &Acidity

CONCOMITANTS

BEFORE	AT START OF	DURING	AFTER

B.Previous History: Changes in Menstrual Cylice

Menarche:

Early/Late

Early Years (first 3-4 Yrs)

Before Marriage:

FMP:

After Pregnancy(ies)

Recent

Complaints related to

Meanrche

After Marriage

C. Climacteric:

Symptoms associated

Pre-Menopause	With Menopause	Post Menopause

D. Abnormal Vaginal Discharges (Leucorrhoea/Lochia)

Type	Quantity	Onset Duration	Color Odour	Stains Acridity	Relation with menses	Modalities	Accompaniments	Obvious reason if any

10. OBSTETICAL HISTORY:

Gravida	Para	Abortion	Death	Live

A. Previous Pregnancies Including Abortion:

No	Age of Conception	Yr. Date and Period Of Pregnancy	Abnormalities in Pregnancy & Treatment Adopted	Labour Events	Mode Of Delivery	Nature Of Purperium

Child

Gender	Birth Weight	Condition of Birth	Congenital Abnormality	Viability	Cause of Death	Lactation History

B. Contraceptive method(s) adopted
(used/inuse/duration)

1. Temporary

2. Permanent (changes of contraceptive method(s) and if so reason, any complaints from use)

C. Present Pregnancy: L.M.P

Date of Quickening

E.D.C

H/O Morning sickness

Other Complaints

11. GENERAL SYMPTOMS:

A. PHYSICALS

I. FUNCTIONAL

1. Appetite :

2. Thirst :

3. Sleep :

4. Dreams

II. ELIMINATIONS

1. Stool :

2. Urine :

3. Sweat :

4. Breath

5. Discharges

6. Abnormal Secretions & Excretions

III . REACTIONS TO

REACTIONS TO	Aversions	Desire	Intolerance/ Sensitive to	Aggravation	Amelioration
Time					
Thermal					
Season					
Meteorological					
Moon Phase					
Places					
Air/Fanning					
Clothing/Covering					
Bathing/Washing					
Food/Drinks					
Undigested Food					
Touch/Pressure					
Posture					
Motion					
Sleep					
Sex					
Spl.Senses					
Eliminations					
Menses					

IV . CONSTITUTIONAL

Physical Makeup	Temperament	Thermal	Side Affinity	Sensation/Tendencies

B. MENTAL GENERAL

1. Will & Emotions including motivations (Love, hat, anger, sadness, fear.fright, anxiety, suspicious, cause, modalities, state, aversion and cravings (excluding food & drinks,) etc.

2. Understanding and Intellect (perception, thinking, consciousness, decision, confidence, speech, motivation, cause, mental state)

B.SYSTEMIC EXAMINATION

- 1.Respiratory system:
- 2.Cardiovascular system:
- 3.Gastro Intestinal system:
- 4.Urogenital system:
5. Skin and glands :
6. Musculoskeletal system
- 7.Central Nervous system:
- 8 . Endocrine:
- 9.Eye and ENT:
- 10.Others:

C.REGIONALS

13. LABORATORY FINDINGS

14. DIAGNOSIS

- ❖ Provisional Diagnosis :
- ❖ Differential Diagnosis:

- ❖ Final Diagnosis (Disease):

15 .DATA PROCESSING

A . ANALYSIS OF CASE

COMMON	UNCOMMON

B. EVALUATION OF SYMPTOMS/TOTALITY OF SYMPTOMS

C. MIASMATIC ANALYSIS:

	PSORA	SYCOSIS	SYPHILIS
Family History			
Past History			
Mind			
Body			

Miasmatic Diagnosis:

D. TOTALITY OF SYMPTOMS

E. HOMOEOPATHIC DIAGNOSIS

16 . SELECTION OF MEDICINE

A. Non Repertorial Approach

B. Repertorial Approach

a)Reprtorial Totality: (Selection of appropriate Repertory, Selection of symptoms for repertorisation, conversion of symptoms into corresponding rubrics for repertorisation)

No	Symptoms	Rubrics	Explanation	Page No

b) Repertorial result:

Medicine						

c) PDF if any

d) Analysis of Repertorial Result

17. SELECTION OF POTENCY AND DOSE

A. Potency

B. Dose

18. PRESCRIPTION

19. GENERAL MANAGEMENT INCLUDING AUXILIARY MEASURES

A. General/Surgical/Accessory:

B. Restrictions (Diet, Regimen etc.):

Disease	Medicinal

20. PROGRESS & FOLLOW UP

DATE	SYMPTOM(S) CHANGES	INFERENCE	PRESCRIPTION

Appendix - V

“Case records are our valuable asset”

SARADA KRISHNA

HOMOEOPATHIC MEDICAL COLLEGE & HOSPITAL

KULASEKHARAM, KANYAKUMARI DIST, TAMIL NADU- 629161

CHRONIC CASE RECORD

O.P. No: 8919/18

UNIT :Pain and Pallium

Date: 1-12- 18

Name: Mr. KASI NADAR

Age: 82 yrs

Sex: Male

Religion: Hindu

Nationality: Indian

Marital status: Married

Occupation: Daily wages cooli

Family size: 3

Diet: Non Veg

Address: Kulasekharam

Phone No (Mobile): 9488870894

FINAL DIAGNOSIS:

Homoeopathic	Chronic miasmatic disease- Psora
Disease	CANCINOMA OF CHEEK

2. initial presentation of illness	
PATIENT'S NARRATION (in the very expressions used by him/her)	PHYSICIAN,S OBSERVATION
Patients complaints as Swelling with tenderness over the cheek in right side since months and burning sensation mouth with difficulty to eat.	Unhygienic Old looking Swelling in the right side cheek Ulcer inside the cheek right side. Whitish discoloration

3. PRESENTING COMPLAINTS

LOCATION (tissues,organs,systems extensions & duration direction & frequency)	SENSATION & PATHOLOGY	MODALITY (>,<) & A/F (=)	CONCOMITANTS IF ANY
<p>Right cheek (sub mandibular region) extending to right ears Since 5 months</p>	<p>Swelling with tenderness Ulcer over mandibular area internally white plaques Swelling under tongue</p>	<p>< Lying on right side < touch < swallowing anything hard</p>	<p>Weakness of whole body</p>
<p>Skin (whole body , except face) Since 5 months</p>	<p>Oval shaped eruption with itching</p>	<p>< perspiration < itching < night >bathing in cold water</p>	

4. HISTORY OF PRESENTING ILLNESS:

Initially, presented before 5 months as decayed tooth extraction. Right side molar tooth was extracted. After which presented with swelling and formation of mass over gums and below the tongue. Patient later presented with intense pain and formation of swelling externally over mandible since 2 months. Patients later consulted another doctor and took biopsy of soft tissue of cheek and was diagnosed with CA right cheek. Patients later got admitted to our OPD. Patient is unable to chew. Anything hard and pain over swelling which extended to right ear. Patient is unaware of his diagnosis.

5. HISTORY OF PREVIOUS ILLNESS

R/A Fever- Takes allopathic medicine

6. HISTORY OF FAMILY ILLNESS

Mother - Asthma

7. PERSONAL HISTORY

A. LIFE SITUATION

Place of birth: Vellamadam

Caste: Hindu

Socio- economic status: Moderate

Nutritional status: Moderate

Dwelling: Kulasekharam

Religion: Hindu

Educational status : Not educated

Marital status: Married

Year of Marriage: 27yrs

Family status: Joint

Father: Died; Mother: Died Siblings: 2 Male:2

Children: 6F, 2M

B. HABITS & HOBBIES

Food: Non vegetarian

Addictions: Tobacco chewing

Sleep: Disturbed

C. DOMESTIC RELATIONS

With family members: Good

With other relatives: Good

With neighbours/friends/colleagues: Good

8. LIFE SPACE INVESTIGATION

Patient is illiterate, born to a middle class family, parents worked as coolie, started working from 8yrs of age helping his elders, married at 27 years of age, he started his habit of chewing tobacco, since 10 yrs of age, while staying with his grandmother, patients is hard working but worried about his present state of health as he could not do his work.

11. GENERAL SYMPTOMS:

A. PHYSICALS

I. FUNCTIONAL

1. Appetite : Decreased
2. Thirst :Decreased
- 3.Sleep : Disturbed
4. Dreams

II. ELIMINATIONS

1. Stool :Irregular ineffectual urging
2. Urine : Decreased in quantity
3. Sweat :Normal

III . REACTIONS TO

REACTIONS TO	Aversions	Desire	Intolerance/ Sensitive to	Aggravation	Amelioration
Time					
Thermal		warm			
Season					
Meteorological					
Moon Phase					
Places					
Air/Fanning	✓				
Clothing/Covering		✓			
Bathing/Washing					
Food/Drinks		Warm			
Undigested Food					
Touch/Pressure					
Posture					

Motion					
Sleep					

IV . CONSTITUTIONAL

Physical Makeup	Temperament	Thermal	Side Affinity	Sensation/Tendencies
	Melacholic	Ambi	Right side	

B. MENTAL GENERAL

Easily angered – uses abusive words

Desire company

Optimistic

Worried – he cannot go to work (Weeps when talking about diseases)

Memory Good

12. PHYSICAL EXAMINATION

A) GENERAL

- Conscious : conscious
- General appearance: weak
- General built and nutrition: Poor
- Height – 162 cm
- Weight – 64 Kg
- BMI -24.4
- Anaemia: Pallor

- Jaundice: Not icteric
- Clubbing: Nil
- Cyanosis: Nil
- Oedema : Nil
- Nails- Deformity
- Gait : steady
- Lymphadenopathy: Nil
- Pulse rate: 64/ min Resp rate: 16/min
- B.P: 110/86 mmhg
- Temp : 98.6 F
- Others: Normal

B.SYSTEMIC EXAMINATION

- 1.Respiratory system: Nothing relevent
- 2.Cardiovascular system: Nothing relevent
- 3.Gastro Intestinal system: Nothing relevent
- 4.Urogenital system: Nothing relevent
5. Skin and glands : Nothing relevent
6. Musculoskeletal system Nothing relevent
- 7.Central Nervous system: Nothing relevent
- 8 . Endocrine: Nothing relevent
- 9.Eye and ENT: Nothing relevent

10.Others: Examination of oral cavity:

Right mandibular swelling, small swelling over submental (Rt side), Tenderness to touch,
lips normal,

Ulcer- over right side yellow plaques, non –healing, socket like appearance (near molar
tooth wisdom teeth)

C.REGIONALS

Hair – Greying

Skin – Whitish eruptions

13. LABORATORY FINDINGS

22- 11- 18 :

Biopsy: Retromolar tissue, Buccal mucosa

Impression :Verrucous carcinoma – CA . Right cheek

14. DIAGNOSIS

❖ Provisional Diagnosis : RIGHT CHEEK CARCINOMA

15 .DATA PROCESSING

A . ANALYSIS OF CASE

COMMON	UNCOMMON
Right cheek- swelling, pain < swallowing < touch	Ulcer with white plaques Right cheek carcinoma App: Reduced Skin : Itching eruptions < night < perspiration

B. EVALUATION OF SYMPTOMS/TOTALITY OF SYMPTOMS

Mental – Easily angered, worried

Physical - Appetite : reduced, Urine : decreased in quantity, Stool: irregular

Particular – Right swelling with pain, < swallowing, < touch, Skin itching, < itching,
< night

C. MIASMATIC ANALYSIS:

	PSORA	SYCOSIS	SYPHILIS
Family History	Easily angered worried		
Past History			
Mind		CA cheek, white plaques	Easily angered
Body	Itching all over body Ulcer on the cheek painful	Stool ineffectual Urine decreased quantity	

Miasmatic Diagnosis:

D. TOTALITY OF SYMPTOMS

Old age, thermal- ambi, cheek- right side, swelling with tenderness, white plaques

Skin itching with eruption, < perspiration, < night, appetite- reduced, stool-

ineffectual urging, urine- reduced inquantity

E. HOMOEOPATHIC DIAGNOSIS

CARCINOMA OF CHEEK

16 .SELECTION OF MEDICINE

A. Repertorial Approach

a) **Reprtorial Totality:** (Selection of appropriate Repertory, Selection of symptoms for repertorisation, conversion of symptoms into corresponding rubrics for repertorisation)

No	Symptoms	Rubrics	Explanation
1	Appetite diminished	Stomach-appetite-diminished	Physical generals
2	Right sideness	Generality-side-right	Physical generals
	Swelling in the cheek	MOUTH Swelling-cheek-inside	particular
	Pain extend on ear	Ear-pain-right	particular
	Itching eruption on right side	Skin-eruption-itching-right	Particular
	Swellin in face	Face-swelling-right	Particular
		Face-pain-jaw	Particular

b) **Repertorialresult:**

Medicine	Merc	Caust	Ars alb	Lyc	Calc	Puls
----------	------	-------	---------	-----	------	------

	10/6	10/5	8/4	7/4	7/4	7/4
--	------	------	-----	-----	-----	-----

17. SELECTION OF POTENCY AND DOSE

A. Potency : According to susceptibility of patient

B. Dose : According to homoeopathic principal

18. PRESCRIPTION

1. **R_x** ARSENICUM ALBUM 0/1-2D ½ hrly two times.
2. **SL** 1 x QID
3. **SD** 1 x BD
4. **SG3** x TDS

19. GENERAL MANAGEMENT INCLUDING AUXILLARY MEASURES

A. General/Surgical/Accessory: Keep personal hygiene, keep oral hygiene, take rich protenasious food, avoid strong stimulences.

B. Restrictions (Diet, Regimen etc.):

Disease	Medicinal
Avoid spicy and hard food.	Avoid coffee and strong stimulence

Follow-up

02/12/2018

Swelling in mouth and right side of mandible is persist. Tenderness present.

Pain extend to the ear, difficulty to open mouth

Whitish plague inside the mouth

Enlarged lymphnode

Appetite – reduced

Thirst- normal

Sleep- disturbed

Stool- difficulty to pass

Urine-normal

Sweat- normal

R_x

ARESINICUM ALBUM 0/2 -2D

SL 1 x QID

SD 1 x BD

SG3 x TDS

01/01/2019

Swelling in mouth and right side of mandible is persist. Tenderness present but feel better.

Pain extend to the ear, difficulty to open mouth feel better

Whitish plague inside the mouth

Enlarged lymph node

Appetite – reduced

Thirst- normal

Sleep- disturbed

Stool- improved

Urine-normal

Sweat- normal

R_x

ARESINICUM ALBUM 0/3 -2D

SL 1 x QID

SD 1 x BD

12/02/2019

Swelling in mouth and right side of mandible is persist. Tenderness present but feel better.

Pain extend to the ear better, difficulty to open mouth feel better

Whitish plague inside the mouth

Enlarged lymph node

Appetite – reduced

Thirst- normal

Sleep- disturbed

Stool- improved

Urine-normal

Sweat- normal

R_x

ARESINICUM ALBUM 0/4 -2D

SL 1 x QID

SD 1 x BD



SARADA KRISHNA HOMOEOPATHIC MEDICAL COLLEGE & HOSPITAL
KULASEKHARAM, KANYAKUMARI DIST. TAMILNADU 629161

EORTC QLQ – H&N43

Name: Age/Sex.....

Op No: Diagnosis: Date:

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. 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
1. Have you had pain in your mouth?	1	2	3	4
2. Have you had pain in your jaw?	1	2	3	4
3. Have you had soreness in your mouth?	1	2	3	4
4. Have you had pain in your throat?	1	2	3	4
5. Have you had problems swallowing liquids?	1	2	3	4
6. Have you had problems swallowing pureed food?	1	2	3	4
7. Have you had problems swallowing solid food?	1	2	3	4
8. Have you choked when swallowing?	1	2	3	4
9. Have you had problems with your teeth?	1	2	3	4
10. Have you had problems because of losing some teeth?	1	2	3	4
11. Have you had problems opening your mouth wide?	1	2	3	4
12. Have you had a dry mouth?	1	2	3	4
13. Have you had sticky saliva?	1	2	3	4
14. Have you had problems with your sense of smell?	1	2	3	4
15. Have you had problems with your sense of taste?	1	2	3	4
16. Have you had problems with coughing?	1	2	3	4
17. Have you had problems with hoarseness?	1	2	3	4
18. Have you had problems with your appearance?	1	2	3	4
19. Have you felt less physically attractive as a result of your disease or treatment?	1	2	3	4

20. Have you felt dissatisfied with your body?	1	2	3	4
21. Have you had problems eating?	1	2	3	4
22. Have you had problems eating in front of your family?	1	2	3	4
23. Have you had problems eating in front of other people?	1	2	3	4
24. Have you had problems enjoying your meals?	1	2	3	4
25. Have you had problems talking to other people?	1	2	3	4
26. Have you had problems talking on the telephone?	1	2	3	4
27. Have you had problems talking in a noisy environment?	1	2	3	4
28. Have you had problems speaking clearly?	1	2	3	4
29. Have you had problems going out in public?	1	2	3	4
30. Have you felt less interest in sex?	1	2	3	4
31. Have you felt less sexual enjoyment?	1	2	3	4
32. Have you had problems raising your arm or moving it sideways?	1	2	3	4
33. Have you had pain in your shoulder?	1	2	3	4
34. Have you had swelling in your neck?	1	2	3	4
35. Have you had skin problems (e.g. itchy, dry)?	1	2	3	4
36. Have you had a rash?	1	2	3	4
37. Has your skin changed colour?	1	2	3	4
38. Have you worried that your weight is too low?	1	2	3	4
39. Have you worried about the results of examinations and tests?	1	2	3	4
40. Have you worried about your health in the future?	1	2	3	4
41. Have you had problems with wounds healing?	1	2	3	4
42. Have you had tingling or numbness in your hands or feet?	1	2	3	4
43. Have you had problems chewing?	1	2	3	4

FORM - 4 : CONSENT FORM (A)

INFORMATION FOR PARTICIPANTS OF THE STUDY

1. Title of the project: “Efficacy of homoeopathy for improving the quality of life in oral cancer patients”.

2. Name of the investigator/guide :

Dr.N.V.Sugathan MD(HOM)

Professor

Department of Practice of Medicine

Sarada Krishna Homoeopathic Medical College and Hospital

Kulasekharam Kanya Kumari District TamilNadu-629161

3. Purpose of this project/ study:

- To know the effect of homoeopathic medicine in improving Quality of Life (QoL) in cancer patients.
- To know the commonly used homoeopathic medicines for the treatment of oral cancer.

4. Procedure/methods of the study:

Total sample of size calculated from disease prevalence patients are selected from the Out Patient Department, In Patient Department and rural centers of Sarada Krishna Homoeopathic Medical College whose suffer from oral malignancies or suspected to that. The patient pre assessment and post assessment are done by Quality of life scale.

5. Expected duration of the subject participation : July 2017 –January 2019

6. The benefits to be expected from the research to the participant or to others and the post trial responsibilities of the investigator:

- a. The participants are investigated to find out he/she is having oral cancer

- b. If a participant is identified to have oral cancer , pre malignant stage or is a known patient with oral cancer, in both cases he/ she will be given an awareness about the risk factors of oral cancer.
 - c. Thus study is a benefit not only to the participant but also to the society as a whole.
 - d. By this study the participant get best quality Homoeopathic treatment for their complaints.
- 7. Any risks expected from the study to the participant:** For the treatment best selected Homoeopathic medicines will be given. So there will not be any adverse effect or risk because of the study.
- 8. Maintenance of confidentiality of records:** I will not disclose identity of the research participants at any time, during or after the study period or during publication. Securely store data documents in locked locations and Encrypt identifiable computerized data. All information revealed by you will be kept as strictly confidential.
- 9. Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled:** Your participation in the study is voluntary and you are free to refuse treatment or withdraw from the study at any time if you are not satisfied.
- 10. Possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned:** Future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or will be shared with others only with your consent.
- 11. Address and telephone number of the investigator and co-investigator/guide :**

Investigator:

Dr. Rajesh R. S.

Department of Practice of Medicine

Sarada Krishna Homoeopathic Medical College and Hospital

Kulasekharam, Kanyakumari District, TamilNadu -629161

Ph. No: 8129297525

Guide:

Dr.N.V.Sugathan MD(HOM)

Professor

Department of Practice of Medicine

Sarada Krishna Homoeopathic Medical College andHospital

Kulasekharam KanyaKumari District TamilNadu-629161

Ph No: 9443558786

12. Signature of investigator:

13. Signature of guide:

14. Signature of HOD:

FORM - 4 : CONSENT FORM (B)

Participant consent form

Informed Consent form to participate in a clinical trial

Study Title: “Efficacy of homoeopathy for improving the quality of life in oral cancer patients”.

Study Number:

Subject’s Initials:

Subject’s Name:

Date of birth/Age:

Please initial

Box (Subject)

i. I confirm that I have read and understood the information sheet dated
_____ for the above study and have had the opportunity to ask question.

ii. I understood that my participation in the study is voluntary and that I am
free to withdraw at any time without giving any reason. Without my medical care or
legal rights being affected.

iii. I understand that the sponsor of the clinical trial, others working on the sponsor’s
behalf the Ethics Committee and the regulatory authorities will not need my permission
to look at my health records both in respect of the current study and any further research
that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access.
However, I understand that my identity will not be revealed in any information released to third
parties or published.

iv. I agree not to restrict the use of any data or result that arise from this study []

Provided such a use only for scientific purpose(s)

v. I agree to take part in the above study.

Signature (or Thumb impression of the subject/legally acceptable
Representative: _____

Date ____/____/____

Signatory's Name: _____

Signature of the Investigator: _____

Study Investigator's Name: Dr .Rajesh R S

Signature of the Witness _____ Date: ____/____/____

Signature of the Witness _____ Date ____/____/____

APPENDIX-IV
SCORE CHART

SL.NO.	OP NO.	QIQ Score	
		Before	After
1	69/16	119	90
2	2166/17	138	121
3	15/17	143	142
4	18/17	131	117
5	24/17	117	68
6	2065/16	119	78
7	32/17	136	102
8	34/17	109	82
9	50/17	143	142
10	51/17	123	115
11	11/18.	101	98
12	14/18	121	108
13	1236/18	114	102
14	28/18	94	88
15	30/15	125	95
16	37/18	130	122
17	2082/15	111	81
18	67/18	115	114
19	76/18	139	94

20	97/18	143	123
21	112/18	155	131
22	115/18	124	113
23	48/18	143	120
24	502/19	121	108
25	95/17	96	65
26	2096/19	115	104
27	1510/19	100	77
28	8919/18	138	120
29	02/HM/D	146	98
30	40/HM/D	128	127

APPENDIX-VIII

MASTER CHART

S L. N O.	OP NO.	AG E	S E X	DIAGNOSIS	HOMOEOPATH IC MEDICINE	POT EN CY	QLQ SCORIN G		INFERENCE	DURATION OF TREATMEN T
							BE FO RE	AF TE R		
1	69/16	68	M	CA TONGUE	OPIUM	10M	119	90	MODERATE IMPROVEMENT	6 MONTHS
2	2166/17	62	M	VERRULOUS CARCINOMA OF CHEEK	PHOSPHORUS	0/1	138	121	MILD IMPROVEMENT & EXPIRED	6 MONTHS
3	15/17	60	M	CA CHEEK	ACID NIRTICUM	0/1	143	142	NO IMPROVEMENT&EXPIRED	3 MONTHES
4	18/17	44	M	CA CHEEK	ARESNICUM ALBUM	0/3	131	117	MILD IMPROVEMENT	6 MONTHES
5	24/17	79	M	CA TONGUE	THUJA	1M	117	68	MARKED IMPROVEMENT	6 MONTHS
6	2065/16	66	M	CA CHEEK	NATRUM MURIATICUM	0/1	119	78	MARKED IMPROVEMENT	6 MONTHS

7	32/17	76	M	CA CHEEK	ACID NIRTICUM	0/1	136	102	MARKED IMPROVEMENT	6 MONTHS
8	34/17	62	M	LEUKLOPLAKIA	MER SOL	0/1	109	82	MODERATE IMPROVEMENT	6 MONTHS
9	50/17	55	M	CA BUCCAL CAVITY	KALI CYNATUM	30	143	142	NO IMPROVEMENT &EXPIRED	3 MONTHS
10	51/17	67	F	CA TONSILS	LACHESIS	0/1	123	115	MILD IMPROVEMENT	6 MONTHS
11	11/18.	68	M	CA TONGUE	OPIUM	30	101	98	NO SINIFICANT IMPROVEMENT DISCONTINUED	3 MONTHS
12	14/18	62	M	CA TONGUE	ARSENICUM ALBUM	0/1	121	108	MILD IMPROVEMENT	6 MONTHS
13	1236/18	65	M	VERRULOUS CARCINOMA OF CHEEK	KALI CYNATUM	30	114	102	MILD IMPROVEMENT	6 MONTHS
14	28/18	77	M	CA ORO-PHARYNX	CALCARIA CARB	30	94	88	MILD IMPROVEMENT	6 MONTHS
15	30/15	36	M	CA HYPOPHARYNX	ACETIC ACID	30	125	95	MARKED IMPROVEMENT	6 MONTHS
16	37/18	58	M	SQ CELL CA CARCINOMA CHEEK	KALI MURIATICUM	30	130	122	MILD IMPROVEMENT	6 MONTHS

17	2082/15	59	M	CA TONGUE	LYCOPODIUM	200	111	81	MARKED IMPROVEMENT	6 MONTHS
18	67/18	80	F	CA TONGUE	THUJA	0/1	115	114	NO IMPROVEMENT &DISCONTINUED	6 MONTHS
19	76/18	72	F	CA CHEEK AND MANDIBLE	NATRUM MURIATICUM	0/1	139	94	MARKED IMPROVEMENT	6 MONTHS
20	97/18	47	F	CA TONGUE	LACHESIS	0/1	143	123	MODERATE IMPROVEMENT &EXPIRED	3 MONTHS
21	112/18	85	M	CA LIP	HYDRASTICS	200	155	131	MODERATE IMPROVEMENT	6 MONTHS
22	115/18	60	M	VERRULOUS CARCINOMA OF SOFT PALATE	ACID NIRTICUM	0/1	124	113	MILD IMPROVEMENT	6 MONTHS
23	48/18	53	M	CA CHEEK	THUJA	200	143	120	MODERATE IMPROVEMENT	6 MONTHS
24	502/19	53	M	CA ORO-PHARYNX	ACID NIRTICUM	0/1	121	108	MILD IMPROVEMENT	4 MONTHS
25	95/17	73	F	ACINIC CELL CA PARITID GLAND	NATRUM MURIATICUM	0/1	96	65	MARKED IMPROVEMENT	6 MONTHS
26	2096/19	48	M	CA ORO-PHARYNX	CONIUM	30	115	104	MILD IMPROVEMENT	4 MONTHS

27	1510/19	61	M	CA GLOTTIS	NATRUM MURIATICUM	200	100	77	MODERATE IMPROVEMENT	4MONTHS
28	8919/18	82	M	CA CHEEK	ARSENICUM ALBUM	200	138	120	MILD IMPROVEMENT	6 MONTHS
29	02/HM/D	60	F	CA GLOTTIS	ARSENICUM ALBUM	0/1	146	98	MARKED IMPROVEMENT	6 MONTHS
30	40/HM/D	60	M	CA CHEEK	ACID NIRTICUM	200	128	127	NO IMPROVEMENT	6 MONTHS