Dentist Handbook
with extracts based on the Continuing Medical Education (CME) programme by

TATA CANCER CARE FOUNDATION

supported by an educational grant from

Pfizer

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Medico-legal Disclaimer

This handbook has been compiled using the CME extracts from clinicians across Tata Memorial Centre, Mumbai; Assam Cancer Care Foundation; Sri Venkateswara Institute of Cancer Care & Advanced Research (SVICCAR) – Tirupati; Ranchi Cancer Hospital & Research Centre (RCHRC) Ranchi, HomiBhabha Cancer Hospital & Research Centre, Varanasi and the Tata Cancer Care Foundation. The contents of this handbook are intended to serve as a reference for educational and training purposes as all the information is provided in good faith.

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About This Handbook

This handbook is specifically developed for the use of Dentists who are the first point of contact for majority of individuals with suspected oral cancers.

Moreover, due to the limited ‘free of cost’ oncology-related platforms currently available to Dentists, this handbook will be of immense importance.

The modules range from the Introduction, Risk Factors, Diagnostic Tools, Prevention and Early Detection of Oral Cancers, Overview of Oral Pre-Malignant Lesions and their Management, Overview of Staging and Management of Oral Cancer, Side Effects of Radiation and Chemotherapy, Tobacco Control, Palliative and Supportive Care, Nutrition and Diet.

Acknowledgement

Thanks to Pfizer for the educational grant provided to conduct the Continuing Medical Education (CME) program aimed at creating greater cancer awareness amongst Dentists, who play a significant role in identifying the early signs and symptoms of oral cancer and in turn, can refer the suspects for further diagnosis and timely treatment, if needed.

Tata Cancer Care Foundation (TCCF) also acknowledges the contributing expert faculty from the Tata Memorial Centre Mumbai; Assam Cancer Care Foundation (ACCF), Assam; Sri Venkateswara Institute of Cancer Care & Advanced Research (SVICCAR), Tirupati; Ranchi Cancer Hospital & Research Centre (RCHRC), Ranchi; Fortis Hospital, Mumbai and our team from the TCCF Corporate Office.

Index

Background

Tobacco related oral cancers are among the top three cancers in India and dentists can play a major support role in the management of these cancers, if they are adequately empowered by appropriate training. This would result in early diagnosis and better outcomes. Further, tobacco cessation service can also be offered by the dentists who are closest to the patients having tobacco related oral pathology.

This training program was conducted virtually, with following key highlights:

- Online live didactic sessions by subject experts;
- Self-learning videos already prepared by the Tata Memorial Hospital being offered through the Omnicurise-learning platform;
- Open interactive doubt clearing sessions;
- Final assessment.

Summary Of The Presentations

CHAPTER 1

INTRODUCTION TO ORAL CANCER AND PRE-CANCER, CANCER FACTSHEET, EPIDEMIOLOGY

Dr. Dulal Kiran Mondal
Consultant Radiation Oncologist
Assam Cancer Care Foundation (ACCF)

Magnitude of the Problem: 6th most common cancer in the world.

India contributes 1/3rd of the total burden.
India: 135k new cases & 75k death every year
70% cases reports in advanced stage (AJCC stage III-IV)

Some commonly seen clinical features:

Let's look at a few types of oral pre cancers:

1. Leukoplakia
2. Proliferative verucous leukoplakia
3. Erythroplakia
4. Oral sub mucus fibrosis
5. Lichen planus

What are oral cancer symptoms?

Oral cancer has several signs and symptoms that may be mistaken for common problems or changes in your mouth. For example, you may notice patches inside of your mouth that you can't scrape away. These patches may be pre-cancerous conditions.

What are these conditions' symptoms?

These conditions all appear as patches in your mouth and throat, but they are different colors. Here's more information:

- Leukoplakia: These are flat white or gray patches in your mouth or throat.
- Erythroplakia: These are slightly raised or flat red patches. These patches might bleed when scraped.
- Erythroleukoplakia: These patches are red and white.

Common signs and symptoms include:

- Sores on your lip or inside your mouth that bleed easily and do not heal within two weeks.
- Rough spots or crusty areas on your lips, gums or inside of your mouth.
- Areas in your mouth that bleed for no obvious reason.
- Numbness, pain or tenderness on your face and neck or in your mouth that occur without apparent cause.
- Difficulty chewing or swallowing, speaking or moving your jaw or tongue.
- Unintentional weight loss.
- Earache.
- Chronic bad breath.

Let's look at the distribution of cancer in India:

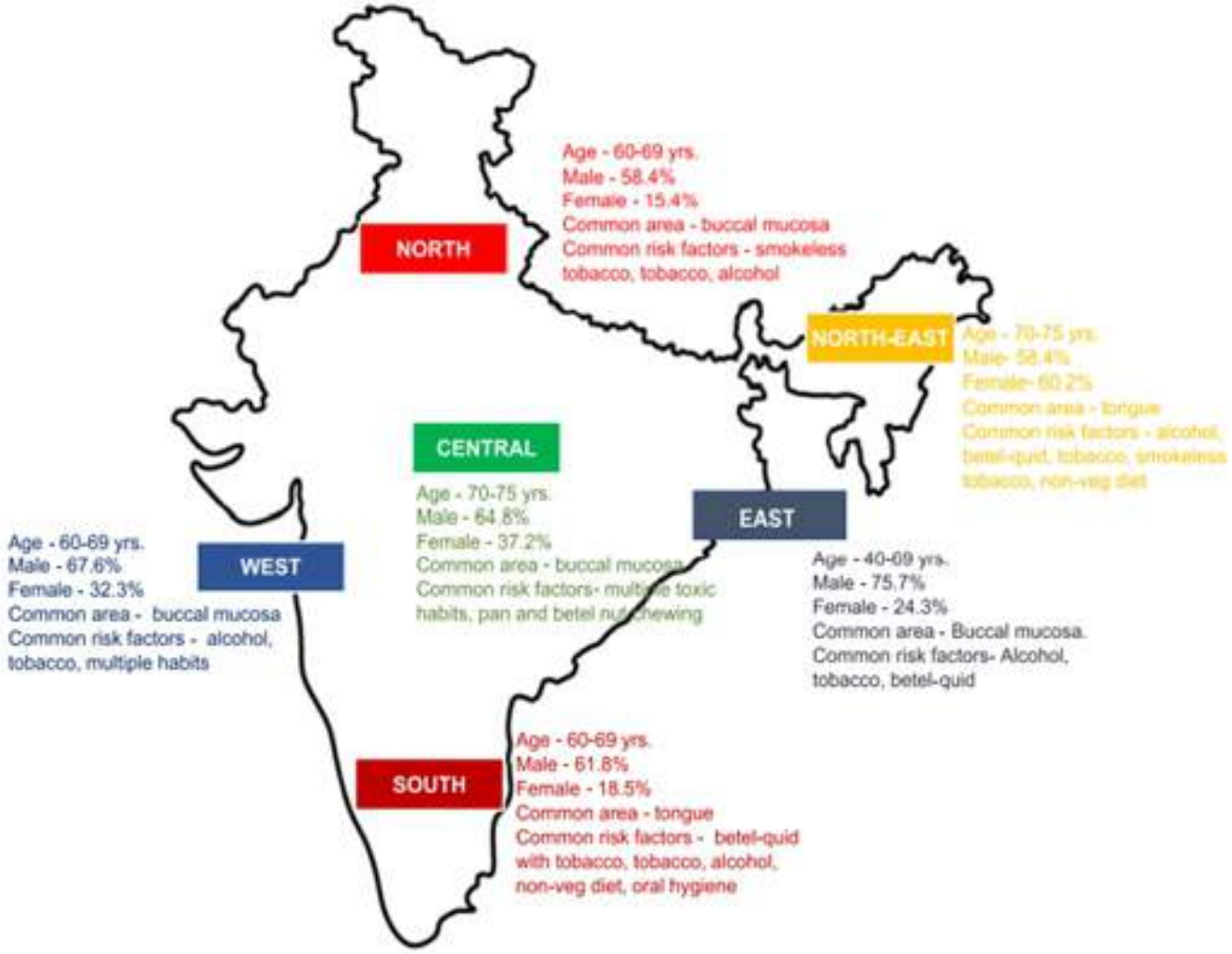


Fig. 1. Distribution of oral cancer across the India.

EPIDEMIOLOGY

1.5 to 4.5% of the total world population
More common in males
In India, in some cities like Kanpur, ~ 60% prevalence
0.7 to 2.9% cases turn malignant annually

Risk Factor of oral Pre-cancers and oral Cancers

Tobacco Smoking	Dietary Factors
Smokeless tobacco use	- Diet low in iron
Betel quid chewing	- Diet low in Vitamin A
Alcohol consumption	- Diet low in Vitamin C
UV light exposure	- High fat diet
Viral factors	Dental Factors
Immunosuppression	- Chronic irritation from jagged teeth
Chronic infection	- Poor dental condition (poor oral hygiene/number of missing teeth>=11)
Occupation	

An easy method of oral cancer screening - is a simple naked eye through examination of the entire oral cavity.

How do healthcare providers treat oral (mouth) cancer?

The three main treatment options for oral (mouth) are surgery, radiation therapy and chemotherapy. Talk to your doctor about the purpose, side effects and ways to manage side effects for all of your options.

Your healthcare provider considers several factors before recommending treatment. Those factors include:

- The kind of oral cancer that you have.
- If the oral cancer you have has spread from the original site to other parts of your mouth and throat or other parts of your body.
- Your general health.
- Your age.

What surgeries treat oral cancer?

The most common surgeries for oral cancer are:

- **Primary tumor surgery:** Healthcare providers remove tumors through your mouth or an incision in your neck.
- **Glossectomy:** This is the partial or total removal of your tongue.
- **Mandibulectomy:** This is surgery for oral cancer in your jawbone.
- **Maxillectomy:** This surgery removes part or all of the hard palate, which is the bony roof of your mouth.
- **Sentinel lymph node biopsy:** This test helps healthcare providers know if cancer has spread beyond the original oral cancer.
- **Neck dissection:** This surgery is done to remove lymph nodes from your neck.
- **Reconstruction:** Surgery that removes large areas of tissue might be followed by reconstructive surgery to fill gaps left by the tumor or replace part of your lips, tongue, palate or jaw. In some cases, reconstructive surgery is done by taking healthy bone and tissue from other areas of your body.

What are other ways to treat oral cancer?

Healthcare providers may combine surgery with other treatments, including:

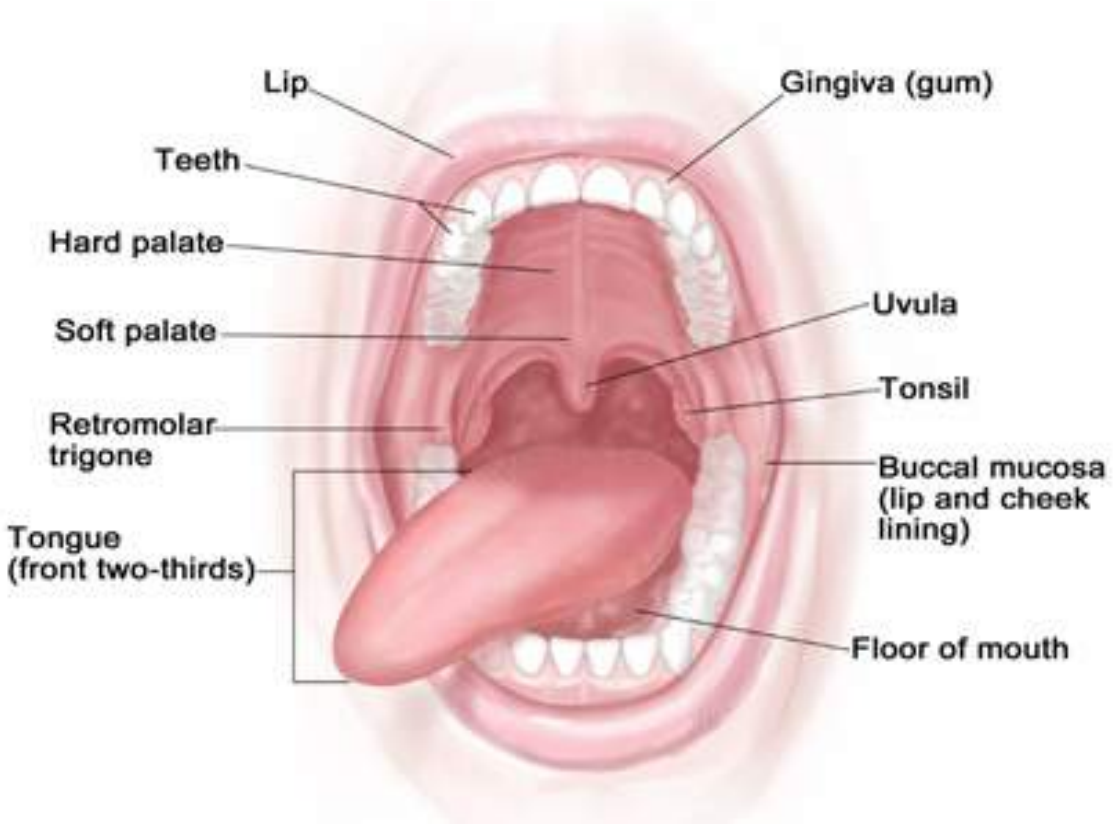
- **Radiation therapy:** Radiation therapy uses strong beams of energy to kill cancer cells or keep them from growing. Your healthcare provider may combine radiation therapy with other treatments.
- **Targeted therapy:** This cancer treatment uses drugs or other substances to precisely identify and attack certain types of cancer cells without hurting normal cells. Monoclonal antibodies are immune system proteins that are created in the lab and used to treat cancer.
- **Chemotherapy:** Your healthcare provider may use anti-cancer drugs that kill cancer cells, including treatments that affect most parts of your body.
- **Immunotherapy:** Immunotherapy is a cancer treatment that engages your immune system to fight the disease. The treatment is sometimes called biological therapy.

CHAPTER 2

DIAGNOSTIC TOOL FOR ORAL CANCER DIAGNOSIS – CYTOLOGY, BIOPSY, SPECIAL STAINING

Dr. Samrat Bordoloi
Consultant Oncopathologist
Assam Cancer Care Foundation

Anatomy Of The Oral Cavity



Cytological Sampling Techniques - Four basic sampling techniques

- Collection of exfoliative cells
- Collection of cells removed by brushing or similar abrasive techniques
- Aspiration biopsy (Fine Needle Aspiration)
- Intraoperative cytology

Indication -

- The principal application of cytologic techniques to epithelial lesions of the oral cavity is the diagnosis of occult carcinomas, not identified or not suspected on clinical inspection. (OPMD)
- Cytologic methods are particularly valuable in screening for occult oral cancer, but may occasionally contribute to the diagnosis of early or unsuspected cancers of adjacent organs.

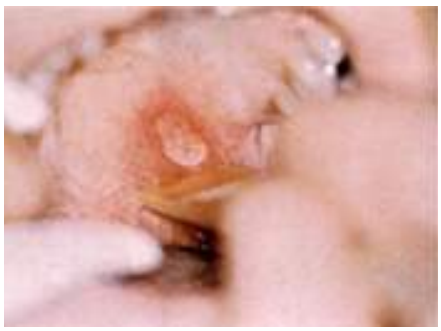
Advantage -

- Relatively inexpensive and easy to perform

Disadvantage -

- Requires a high level of expertise for morphological assessment.

Technique - Exfoliative/Abrasive Cytology



Scraping a suspicious lesiona

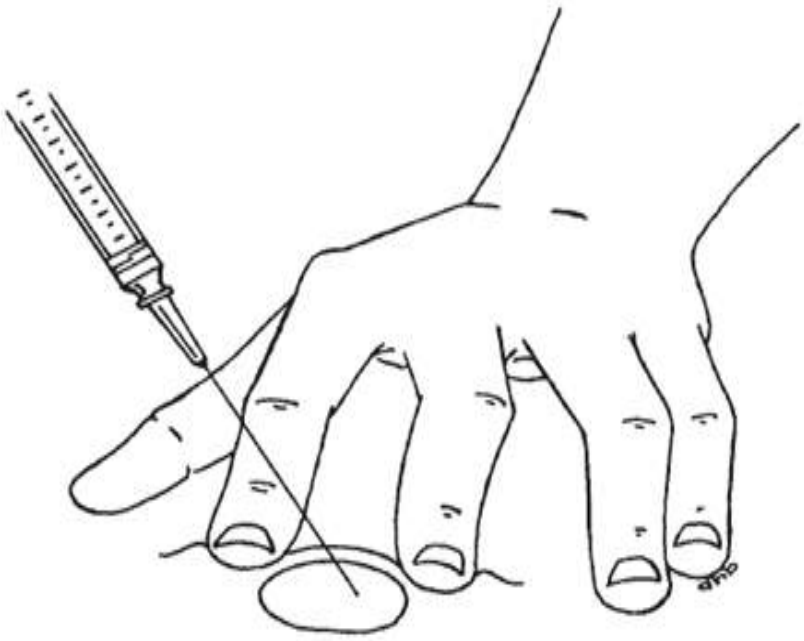
Gentle smearing onto a slide

Using a fixative

Let's look at some tools and techniques used to diagnose oral pre cancers and oral cancers:

Tools - Exfoliative/Abrasive Cytology

Technique - Aspiration Biopsy (FNA)



Immobilization of small lesions (1 to 2.5 cm) using the fore fingers and middle fingers. Stretch the overlying skin and hold it down firmly, preventing the lesion from moving during the procedure.

Intraoperative Cytology

- Intraoperative consultations by frozen sections are a very important aspect of practice in surgical pathology.
- Supplementing or replacing frozen sections by cytologic touch, scrape, or crush preparations.
- This technique is not so useful in oral cancers. Predominantly used in CNS tumors.
- Routine Stains used in Cytology.

Comparison of May-gruenwald-giemsa (mgg), Hematoxylin-eosin, and Papanicolaou Stains

Factors	MGG	Hematoxylin-Eosin	Papanicolaou
Preparation of material	Air-Drying	Alcohol fixation	Alcohol fixation
Cytoplasmic features	Brings out a variety of cytoplasmic granules and inclusions	Offers little cytoplasmic differentiation	Brings out cytoplasmic keratinization
Nuclear features	Chromatic features difficult to assess; air-drying may induce artifacts	Tends to overstain nuclei unless carefully performed	Excellent identification of nuclear features
Nucleoli	Readily visible as pale intranuclear structures	Adequate, sometimes difficult to see in hyperchromatic nuclei	Adequate, sometimes difficult to see in hyperchromatic nuclei
Mucus and colloid	Well visualized	Require special stains	Require special stains
Familiarity to users	Stain familiar to hematologists	tain familiar to tissue pathologists	Stain familiar to cytopathologists

Principal Morphologic Differences Between Normal Cells and Cancer Cells

	Benign Cells	Cancer Cells
Cell size	Variable within physiologic limits	Variable beyond physiologic limits
Cell shape	Variable within physiologic limits and depends on tissue type	Abnormal shapes frequent
Nuclear size	Variable within limits of cell cycle	Significant Variability (anisonucleosis)
Nucleocytoplasmic ratio	Variable within physiologic limits	Commonly altered in favour nucleus
Nuclear shape	Generally spherical, oval, or kidney-shaped	Aberrations of shape and configuration
Chromatin texture (nondividing nucleus)	Finely granular texture, “transparent”	Coarsely granular texture, “opaque”
Hyperchromasia	Rare	Common
Multinucleation	Not characteristic	Not characteristic
Nucleoli	Small, regular in shape, limited in number	Enlarged, of irregular configuration, increased in number

Biopsy

Types of Biopsy performed in Oral Lesions -

- Incisional Biopsy/Punch Biopsy - Part of the lesion is removed.
- Excision Biopsy -
  - Involves surgical removal of the tumour and part of normal tissue around it.
  - The specimen should always be oriented.

Advantage-

- Most accurate of assessment

Disadvantage-

- Invasive
- Bleeding
- Risk of infection

Oral Punch Biopsy Procedure:

1. Anaesthesia - Topical or Local Anaesthesia at the biopsy site
2. Incision-
   a. **Location-**
   i. Biopsy the most abnormal appearing site within a lesion or the edge of the lesion to obtain both normal tissue and lesional tissue.
   ii. When performing on gingiva, avoid the gingival margins.
   b. **Direction-**
   • Biopsy punch should be incised perpendicular to the lesion
   c. **Depth-**
   • The standard depth for an oral mucosa punch biopsy would be 4-5 mm.
3. Removal of Specimen - Gently lift the specimen with a 21G needle and cut the base with a scalpel blade.

1. Transfer - Transfer in a fixative (10% buffered formalin for Routine H&E)

Clinical Diagnosis	Special Considerations
Oral squamous cell carcinoma	Ulcer margin including normal epithelium; 4–5 mm in diameter and depth (because of hyperkeratosis)
Leukoplakia/erythroplakia	Both red and white areas in speckled lesions; biopsy from most representative areas.
Oral lichen planus	Gingiva and erosive areas to be avoided

Special Stains

Objectives of doing a Special Stain-

1. Identify suspicious areas for sampling
2. Differentiate Carcinoma in situ from microinvasive SCC
3. Identify key features of malignancy including abnormal keratinization and mitotic figures.
4. Demonstrate special constituents like mucin types in salivary gland tumors
5. Identify extracellular matrix changes.
6. Identify surface, cytoplasmic or nuclear structures by Antigen-Antibody reaction (Immunohistochemistry / IH Vital Staining to identify suspicious areas)
7. Dyes are used to stain living cells.
8. If done in-vivo - “Infravital”; if ex-vivo - “Supravital”
9. Stains certain structures within the cells.
10. Dyes used in Infravital staining -
    1. Toluidine Blue
    2. Lugol’s Iodine
    3. Methylene Blue
    4. Acetic Acid
    5. Rose Bengal

11.C)

Lugol's Iodine-

- The dye stains the glycogen in normal squamous epithelium a dark brown.
- Areas that are unstained particularly those that are larger than 5 mm are likely to be dysplastic /malignant and can be targeted for biopsy.

Toluidine Blue-

- Affinity for nucleic acids, the principle is based on the fact that dysplastic and neoplastic cells contain quantitatively more nucleic acids than normal tissues.
- Interpretation: Positive- dark royal blue; Doubtful- pale blue; Negative- no colour change.

Acetic Acid (3 to 5 %)-

- Causes reversible coagulation / precipitation of cellular proteins.
- Epithelium that contains a lot of cellular proteins, acetic acid coagulates these proteins, which may obliterate the colour of the stroma.
- Resulting aceto- whitening is seen distinctly as compared with the normal pinkish colour of the surrounding normal squamous epithelium.

Rose Bengal-

- Originally used to delineate the extent of the corneal and conjunctival neoplasms.
- Stains the cells, wherever there is poor protection of the surface epithelium by the preocular tear film.
- A primary epithelial abnormality i.e, dysplasia, metaplasia, virus infected cells or other forms of epithelial keratitis, can render the inability of epithelium to interact with the mucous layer, thus allowing the RB staining.

Basement membrane stains - Carcinoma in situ vs Invasion

- Basement membranes are composed of Type IV collagen
- Associated with large amounts of Carbohydrate complexes
- Stains used to highlight the BM-
  - Periodic Acid Schiff (PAS) Stain
    - Stains the carbohydrate component.
  - Methenamine Silver Stain
    - Based on oxidation - aldehyde reduction
    - Carbohydrate is oxidized to Aldehyde. Silver ions attached to the Carbohydrate groups reduced to metallic silver.
  - Gridley Stain
  - Bauer-Feulgen Stain
  - Martius Scarlet Blue trichrome
  - Azan Trichrome

Identify foci of abnormal keratinization

- Stains used to demonstrate keratin-
  - Ayoub-shklar method
  - Dane-Herman method
  - Modified Papanicolaou method

All these stains use Orange G as the main stain with modifications using Phloxine B, Alcian Blue

CHAPTER 3

PREVENTION AND EARLY DETECTION OF ORAL CANCER, ROLE OF TATA TRUSTS CANCER CARE INITIATIVE IN ORAL CANCER CONTROL

Dr. Paul Sebastian
TCCF

1/3rd of global burden of oral cancer is in India

- 90% are tobacco related
- More than 70% are in advanced stages at initial presentation (Stage III & IV)
- Poor survival and high mortality
- Lack of access to good quality affordable care

Late stage diagnosis and high mortality

- Lack of cancer awareness;
- Lack of access to good quality affordable cancer care;
- Creating awareness, prevention and early detection and improving access to diagnosis and good quality; affordable treatment would result in down-staging of cancer and reduction in mortality.

Tobacco use and oral cancer

- Approximately 90% of patients with oral cancer have a history of tobacco use;
- Smoked forms and smokeless forms;
- Compared to non-smokers, tobacco users have a 4–5-fold increased risk for cancer;
- Risk of cancer is related to the frequency and duration of tobacco consumption.

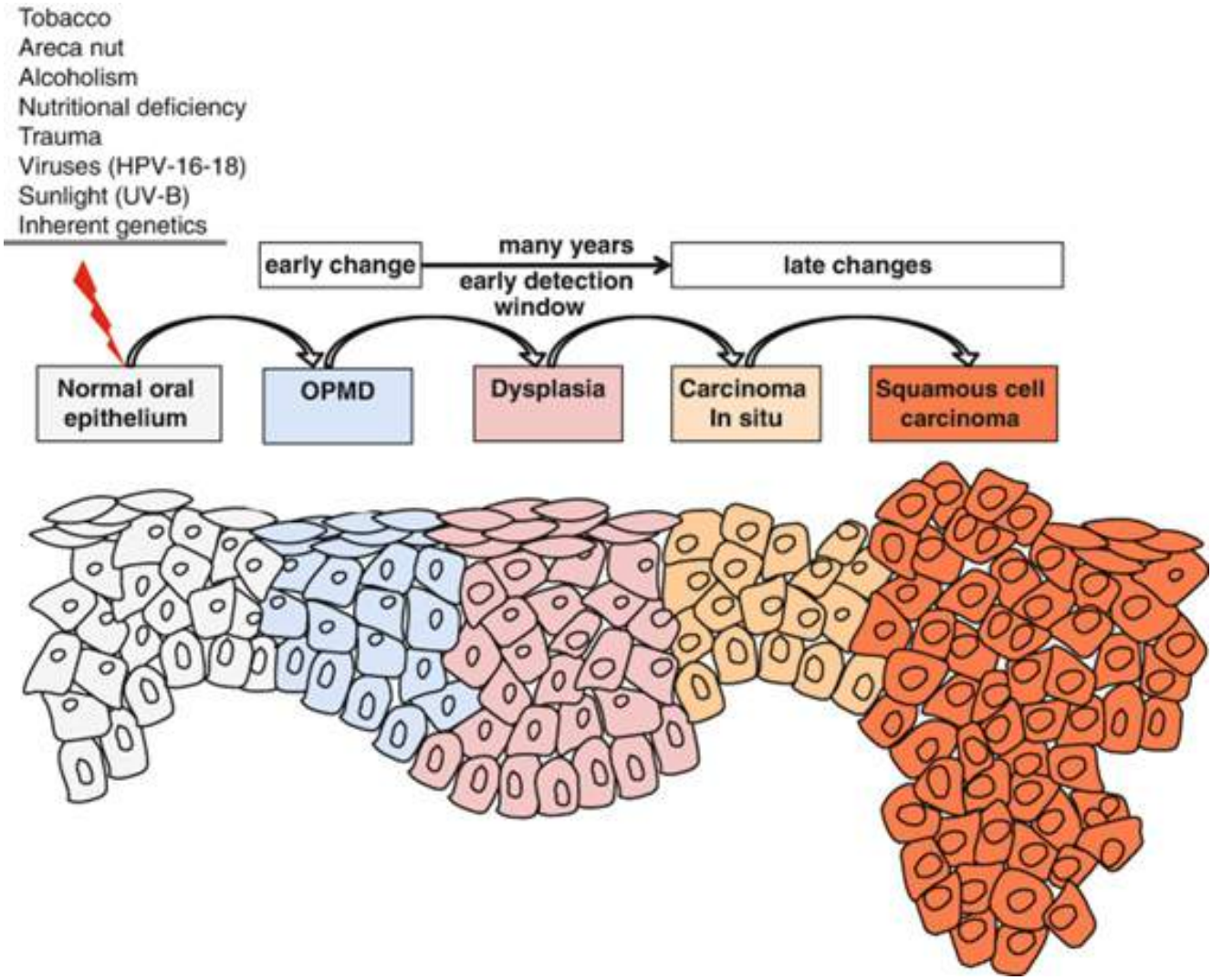
Smokeless tobacco

- Smokeless (chewing) tobacco increases the risk of cancer of the oral cavity;
- Various forms of smokeless tobacco are available;
- In India, 50%–60% of oral cavity cancers are attributed to smokeless tobacco.

Alcohol & Oral Cancer

Alcohol use independently increases the risk of HNSCC, with 1%–4% of cases attributed to alcohol alone.
It specifically increases the risk of hypopharyngeal cancer.
It acts synergistically with tobacco, resulting in an approximately 35- fold increase in HNSCC risk in heavy smokers (>2 packs / day) and drinkers (>4 drinks / day).

Natural history of oral cancer



Tobacco control

- Target the youth to prevent initiation of tobacco habits
- ToFEI implementation
- Tobacco cessation counselling and therapy
- Enforcement of COTPA law

Oral Potentially Malignant Disorders (OPMD)

OPMDs are associated with increased risk of occurrence of cancer
Lesion - Morphologically altered tissue in which cancer is more likely to occur than its normal counterpart
Condition - Generalised state of the body which is associated with an significantly increased risk of cancer

Tata Trusts' Cancer Care Program

- Vision: To transform cancer care in India
- Mission: Improve the quality of life for cancer patients and kin by providing affordable, accessible and high quality care

Distributed network - Locations and configurations

	Completed Projects	
1	IRCIRC, Varanasi	L2
2	MTMH Jamshedpur	L2
3	Centre for Oncopathology	Apex R&R Lab
4	Ashwini Hospital Upgradation	L3
5	MPMMCC, Varanasi	L1
6	Navsari	Advisory
7	Yenepoya	Custom L3
8	Cachar	Custom L3
9	AMCH Dibrugarh	Custom L3
10	Tezpur	L3
11	Jorhat	L3
12	Lakhimpur	L3
13	SVICCAR, Tirupati	L2
14	RCHRC	L2
15	Dibrugarh	L2
16	Barpeta	L2
17	Kokrajhar	L3
18	Darrang	L3
19	Lakhimpur	L3
20	Jorhat	L3
21	Tezpur	L3
	Ongoing Projects: Assam	
22	SCI Guwahati	L1
23	Diphu	L2
24	Dhubri	L3
25	Goalpara	L3
26	Golaghat	L3
27	Tinsukia	L3
28	Sibsagar	L3
29	Nagaon	L3
30	Nalbari	L3
	Ongoing Projects: Non Assam	
31	Chandrapur	L2

Geography of public outreach programs

1. Assam
2. Ranchi
3. Chandrapur
4. Tirupati

Goal (Impact) (aligned with vision of Cancer Care Program)
One-third reduction in cancer mortality

- 5 years - Midline assessment
- 10 years - End line assessment

Outcome (aligned with objectives of Cancer Care Program)

I. Prevention and awareness

1. 50% of population have knowledge and adopted healthy lifestyle for cancer prevention (Midline survey-5 years).

II. Screening and Early detection

1. 50% of the 30 - 65 years population have been screened once in last 5 years.
2. 70% cancers detected in target population(30 – 65 years) in early stage, where cancer has not Progressed to other body parts (End line assessment-10 years).

III. Referrals and Follow-ups

1. 80% reduction in direct cost related to cancer treatment (Mid line survey-5 years)
2. 50% reduction in lost to follow up of cancer patients in 5 years.

Health Kiosk

- **Prevention and Clinical Services:**
  - HTN, DM, BMI check-Up
  - Oral, breast & cervical cancer screening
  - Cancer awareness & sensitization
  - Health promotion activities
  - Tobacco cessation counseling

Catchment Team

Designation	Roles and Responsibilities
District Program Manager	• Liaison with District NCD (Non-Communicable Diseases) Cell. Overall implementation of program activities, monitoring and evaluation
Program Coordinator-Screening Camp	• Work closely on the micro plans of camps, awareness campaigns with ASHAs (Accredited Social Health Activist) and MPWs (Multipurpose Health Worker).
Dentist	• Screening of OPMD (Oral Potential Malignant Disorder) and suspect oral cancers, health education on tobacco control and oral hygiene
Staff Nurse	• Screening of breast cancer and cervical cancer through Clinical breast examination (CBE) and VIA (Visual inspection with acetic acid) tests.
Kiosk Nurses	• Screening of NCDs at health kiosk for the persons visiting the health facility (opportunistic screening). Providing cancer awareness and tobacco cessation counselling to the visitors at health facility.
Tobacco Control Coordinator	• Will work closely with the NTCP (National Tobacco Control Program) and non NTCP components of tobacco control
Patient Navigator	• Ensure referral and follow up of suspected cases. Activating referral linkages, diagnostic services, ambulance services
Data Entry Operator	• Data entry in Patient Tracking and Referral App

CHAPTER 4

BIOPSIES IN ORAL LESIONS – PRINCIPLES, TECHNIQUES AND PRECAUTIONS

Dr. Kinshuk Chatterjee
Dept. of Head and Neck Surgical Oncology
Tata Memorial Hospital, Mumbai

- Oral cancer is the sixth most common cancer in the world and India contributes to One third of all cases globally.
- Mostly seen in adult males in the age group of 60-70 years.
- Recently, there has been an increase in trend in the younger age groups and also amongst women.
- Tobacco and alcohol are proven to be the two most important causative factors.
- In India, majority of the cases present in advanced stage and the 5-year overall survival in such stages is poor.
- Hence, it is of paramount importance to screen for oral cancers, identify potentially malignant disorders and early stages of oral cancers to offer a cure without much functional and cosmetic morbidity to the patients The French dermatologist Ernest Besnier coined the term biopsy in 1879.
- The term is derived from Greek – bios meaning “life” and opsis meaning “sight.”
- Defined as a surgical procedure to obtain representative tissue from a living organism for its microscopical examination, usually to perform a diagnosis

Why is biopsy important?

- Cornerstone of diagnosis and management of oral cancers and oral potentially malignant disorders (OMPD).
- Histological examination of the tissue from the biopsy is the initial step to confirm or refute a clinical diagnoses.
- Assists in the development of a treatment protocol for patients with oral cancer or OPMDs.
- Biopsies done during and after treatment are critical to establish a successful treatment outcome or to identify failures and to detect recurrences.

Types of biopsies

- Features of the condition
- Direct biopsy: A mucosal lesion apparent at the surface of the mucosa and can be accessed from the surface
- Indirect biopsy: An abnormality deep in the tissue and covered by normal-appearing mucosa

Tissue needing surgical removal

Soft tissue
- Punch biopsy
- Incisional biopsy
- Excisional biopsy

Blood: Liquid biopsy

Hard tissue
- Needle core
- Trephine
- Curettage / enucleation

Timing of the biopsy
- Pre-operative
- Intraoperative (Frozen section biopsy)
- Postoperative (during follow-up or surveillance)

Clinical assessment for a biopsy
Local Examination

- A definitive clinical diagnosis cannot be made.
- It was thought to be an inflammatory condition but has not responded to treatment.
- It has persisted for more than 2 weeks.
- It is a new growth, an ulcer, or a pigmentation that has been progressively increasing in size.
- It is a white or red patch that requires pathology confirmation.
- It is any soft tissue or hard tissue alteration associated with paresthesia or anesthesia.

Biopsy not indicated

- Variations from normal such as Fordyce spots or granules
- Inflammatory conditions, that respond to treatment, such as pericoronitis.
- Reactive or trauma-induced mucosal disorder that responds to removal of local irritants such as a sharp tooth or prosthesis
- Other known benign disorders that have pathognomonic clinical presentations, e.g., geographic tongue and leukoedema.

Clinical assessment for a biopsy
Patient Assessment

- History of allergies to any specific medications
- History of any recent surgeries
- History of comorbidities
- History of any ongoing medications (“blood thinners”)

Adjunctive diagnostic aids

- Vital staining-- Toluidine blue
- Tissue reflectance-chemiluminescence—ViziLite
- Autofluorescence—Velscope
- Narrow band imaging (NBI)
- Tolonium chloride or toluidine blue is the most widely used vital staining method
- Mucosal abnormalities having significant cell proliferation usually take up and retain the dye as it stains the nucleic acid because of acidophilic properties
- retention of toluidine blue is a strong predictor for high risk of malignant conversion, even when there was no or mild dysplasia microscopically, and correlated with high-risk molecular changes

Tissue reflectance + Chemiluminescence – Vizilite

- Basis:
  - Absorptive and reflective properties of light change based on abnormal changes in metabolic and structural changes in tissues
  - Oral Potentially Malignant Disorders (OMPDs) harboring OSCC or Oral epithelial dysplasia (OED) have a differential tissue reflectance as compared to normal mucosa
- First used as adjunct for the evaluation of cervical neoplasia
- Adapted for use in the oral cavity

Autofluorescence - Velscope
Principle:

- Autofluorescence: natural emission of light by biological molecules (Fluorophores) when excited with appropriate wavelength of light

- Fluorophores of oral mucosa- collagen, reduced form of nicotinamide, flavin adenine dinucleide (FAD), porphyrins, elastin, keratin;
- When fluorophores are excited by light of an appropriate wavelength (eg. blue), they emit their own light at a longer wavelength (eg. green) (Stoke's law fluorescence: wavelength emitted > wavelength excitation);
- Unhealthy mucosal tissue-abnormal fluorescence pattern.

Narrow band Imaging (NBI) Endoscopy–guided biopsy

- Current gold standard for endoscopic visualization of vessel networks;
- Developed by Olympus MSC, Japan 2003;
- Endoscopic optical imaging enhancement technology that enhances visualisation of mucosal and submucosal vasculature and neoangiogenesis in abnormal tissue by using a colour filter to narrow the bandwidth of spectral transmittance.

Tissue Biopsy

- Supersedes fine needle aspiration cytology as the sample obtained in biopsy can assess the tissue morphology unlike FNAC;
- Less chances of sampling error leading to less false negative results;
- Moreover, specimen obtained by biopsy can be subjected to immunohistochemistry, if the clinical condition demands.

Common types of Tissue biopsies

- Punch biopsy-Scalpel or laser is used to cut the tissue in incisional or excisional biopsy;
- Incision biopsy-For diagnostic purpose, scalpel is preferred over laser;
- Excisional biopsy-In punch biopsy, a circular blade is used in rotatory motion;
- Biopsy needs to be taken from the representative area of the lesion, preferably including both normal and abnormal tissue;
- 2-3 mm of normal tissue along with the abnormality is sufficient for a lesion which is thought to be benign;
- 5 mm of normal tissue is required ideally when dealing with a clinically suspicious lesion.

Advantages

Simple and easy to use for single or multiple biopsies and are not expensive

The smaller-diameter punches may not need sutures or if necessary only one or two sutures suffice and they are excellent for very friable mucosal abnormality

Limitation

Have to be directed perpendicular to the mucosa to obtain a representative core of tissue

Post Procedural Instructions

- Avoid hot and spicy food for a day;
- To sip cold water frequently for the first 2 hrs of the procedure and have an ice-cream;
- To report to emergency services if any bleeding occurs.

Incisional and excisional biopsy

- Same technique with a slight procedural difference;
- In incisional biopsy, a part of the lesion is removed for diagnostic purpose;
- In excisional biopsy, the entire lesion is removed;
- An incisional biopsy should be preferably deep enough to include the epithelium and sub-epithelial connective tissue;
- Care should be taken to avoid broad and shallow biospies;
- **Single vs multiple incisional biopsies.**
- Large mucosal abnormality (>1 cm) with uniform surface appearance and consistency on palpation—single incisional biopsy from the most representative area;

Large mucosal abnormality with diverse surface features and varying consistency—multiple incision biopsies.

Technique

- Selection of proper place
- Patient positioning
- Setting up of equipments
- Local (or general) anesthesia as required
- Choosing the most representative area
- Obtaining the specimen
- Hemostasis
- Fixation of specimen and transport to the pathologist
- Post procedure advices and patient discharge

Biopsy submission for histopathology…

- Appropriate fixation of tissue is paramount
- Inappropriate fixation (leading to autolysis) and transport can cause distortion of morphology and false results
- Most commonly used fixative is 10% neutral buffered formaline
- Tissue is placed in formalin after it has been rinsed in a saline bowl to get rid of blood etc
- If an intraoperative frozen section is being done, tissue is sent to the pathologist directly without fixation

Biopsy requisition form...

- Patient's demographics (age, gender, ethnicity, occupation)
- History of the chief complaint
- Relevant medical, personal (habits), and social history
- Description of the OPMD / malignancy (site, size, color, and surface changes)
- Physical examination findings (tenderness / pain, consistency, induration)
- The outline of the OPMD / malignancy can be drawn on a template cartoon (with or without the regions marked)
- Information pertaining to the orientation of the tissue, if needed, should also be made with a diagram and/or using a suture in the specimen

Where can things go wrong?

- Miscommunication between the physician and the patient
- procedure not properly explained
- informed consent not obtained
- post procedure advices not given
- post procedure analgesics not prescribed
- Surgical checklist
- Filling up an incorrect pathology requisition form
- Multiple times inadequate biopsy specimens

Take home messages.

- Biopsy is an important diagnostic procedure and forms the cornerstone of diagnosing and managing oral cancers and OPMDs.
- A thorough understanding of the biopsy principles, procedures, and medicolegal issues associated is imperative for the practitioner and a foundation for good clinical practice.
- Adjunctive procedures aid in taking an ideal biopsy and add to visual examination and clinical evaluation.
- Representative tissue sample needs to be obtained and properly sent to the pathologist.

CHAPTER 5

POTENTIALLY MALIGNANT DISORDERS OF ORAL CAVITY AND THEIR MANAGEMENT

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- Tobacco related oral cancer is major burden worldwide (3% of all malignancies worldwide).
- Most common cause of cancer in men in Indian subcontinent.
- Oral Carcinoma is now known to arise de novo.
- **Early detection and prevention** has great potential in decreasing incidence and overall survival
- Lack of awareness and absence of knowledge in health care providers contribute to diagnostic delay

Definitions

- Precancerous lesion- 'a morphologically altered tissue in which oral cancer is more likely to occur than in its apparently normal counterpart'
- Precancerous condition – 'a generalized state associated with a significantly increased risk of cancer'.
  But not all precancerous lesions and condition will turn into malignancy.
  So WHO working group in 2005 abandoned these terminologies and recommended new term potentially malignant disorders.

Some examples:-

- Premalignant Lesions
  - Leukoplakia
  - Erythroplakia
  - Exophytic Verrucous Hyperplasia
  - Reverse Smoker's Palate
  - OSMF
  - Candida Leukoplakia
  - Actinic Cheilitis

- Premalignant Conditions
  - Lichen Planus
  - DLE
  - GVHD / Immunodeficiency
  - XP
  - Plummer Vinson Syndrome
  - Syphilis
  - Epidermolysis Bullosa

Etiology

Extrinsic	Intrinsic factors
Tobacco, areca nut	Genetic
Alcohol	Immunosuppression- organ transplant/ HIV
Virus- HBV,HPV,HIV	Malnutrition- Iron ,Vit A,B,C Deficiency
Bacteria- Treponema pallidum	
Fungus- Candida	
UV rays – **misconception;** it is known to cause lower lip Ca, and is not an etiological factor in carcinogenesis of the labial mucosa	
Chronic irritation due to sharp teeth	

Epidemiology

- Prevalence-
- Overall worldwide prevalence = 4.47%
- Most common = OSMF (4.96%) > Leukoplakia (4.11%)
- Regionally: Highest prevalence rate in Asian (10.54%) > South American/Caribbean populations (3.93%).

  Mello, FW, Miguel, AFP, Dutra, KL, et al. Prevalence of oral potentially malignant disorders: A systematic review and meta-analysis. J Oral Pathol Med. 2018; 47: 633– 640.

- More common in males (prevalence of 59.99%) 1
- Average age 50-59, 5-years earlier than oral Ca.
- Recent study shows 1-5% PMD occur in younger generation<30. 2
- Most common site for PMD in India - Buccal mucosa < Tongue < Palate < Floor of mouth.

Leukoplakia

WHO (1994)
A white patch or plaque that cannot be characterized clinically or histologically as any other disease.

WHO (2005)

A white plaque of questionable risk having excluded (other) known diseases or disorders that carry no increased risk for cancer1

Epidemiology

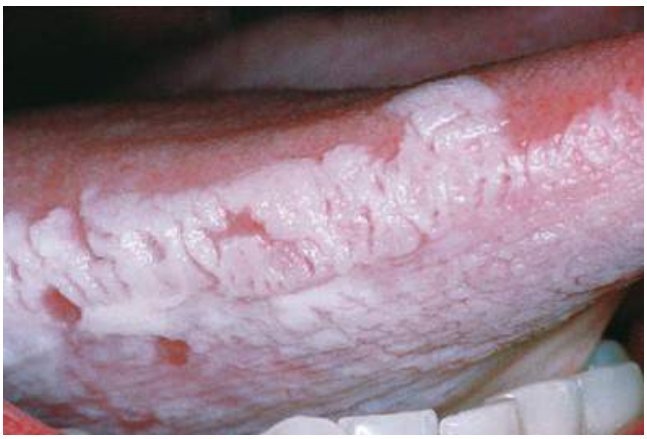
- 4th to 6th Decade
- Males > Females

Annual Malignant transformation rate 1.56% (Overall 8.6%)2

Classification

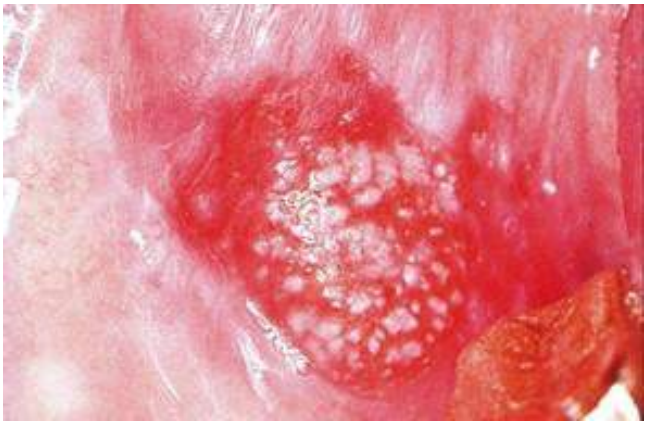
1980 WHO classification:

Homogenous leukoplakia-lesion that was uniformly white and unscrapable.



Non homogenous leukoplakia- lesion predominantly white and speckled with red

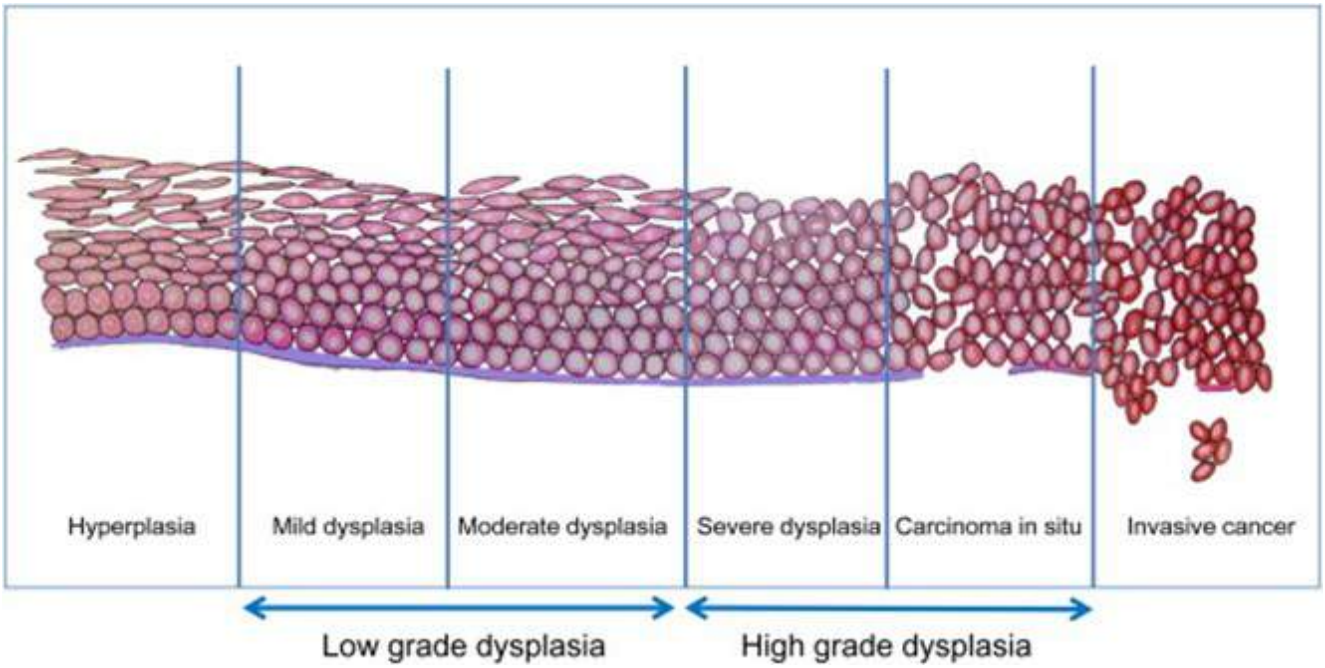
- Speckled
- Nodular
- Verrucous



Differential diagnosis of leukoplakia

White sponge nevus
MorsicatioBuccarum - Habitual cheek – lip biting known, irregular whitish flakes with jagged out line
Chemical injury
Acute pseudomembranous candidosis
Leukoederma
Lichen planus (plaque type)
Lichenoid reaction
Discoid lupus erythematosus
Skin graft
Hairy leukoplakia
Leukokeratosis nicotina palate

Stages in leukoplakia



Risk factors of malignant transformation

- Female gender(for unknown reason 47% of women show malignant transformation)
- Long duration of leukoplakia
- Leukoplakia in non-smokers
- Location on the tongue and/or floor of the mouth
- Size > 200 mm2
- Non-homogeneous type
- Presence of epithelial dysplasia
- DNA aneuploidy

Management

Cessation of risk activities and strict surveillance
Recurrence has been reported in approximately 7%-38% of cases independent of the treatment approach2.

Surgical excision

- Scalpel excision
- Laser surgical excision
- Cryo-fulguration
- Vaporisation

Treatment

Medical treatment

a. Topical

- Vitamin A
- Bleomycin
- Tretinoin/ Isotretinoin

b. Systemic

- Anti-inflammatory agents
- CURCUMIN
- Antimycotic agents
- Carotenoids
- Vitamins

Erythroplakia

WHO definition 1978

- "A fiery red patch that cannot be characterized clinically or pathologically as any other definable disease."
- Etiology – Tobacco, Alcohol
- Malignant Transformation Rate – 33.1% (excluding dysplastic les33% malignant transformation rate.
- On biopsy most of lesion shows carcinoma or severe dysplasia.

Shear Classification

1. Homogeneous: Lesion that appeared flat, velvety, with a uniformly red appearance.
2. Granular: Red lesions with granular surface
3. Speckled (Erythroleukoplakia): Predominantly red lesion speckled with white spots.

Epidemiology

- Prevalence vary between 0.02% and 0.83%.*
- Mainly occur in middle aged and elderly.
- No distinct gender preference.
- Malignant Transformation Rate – 33.1% (excluding dysplastic les33% malignant transformation rate.

Differential Diagnosis

- Erythematous candidiasis (denture-associated somatitis)
- Erythema migrans
- Erosive disorders
- Desquamative gingivitis
- Discoid lupus
- Erosive lichen planus
- Pemphigoid

Oral Submucous Fibrosis

A chronic, insidious disease that affects the oral mucosa, initially resulting in loss of fibroelasticity of the lamina propria and as the disease advances, results in fibrosis of the lamina propria and the submucosa of the oral cavity along with epithelial atrophy'.

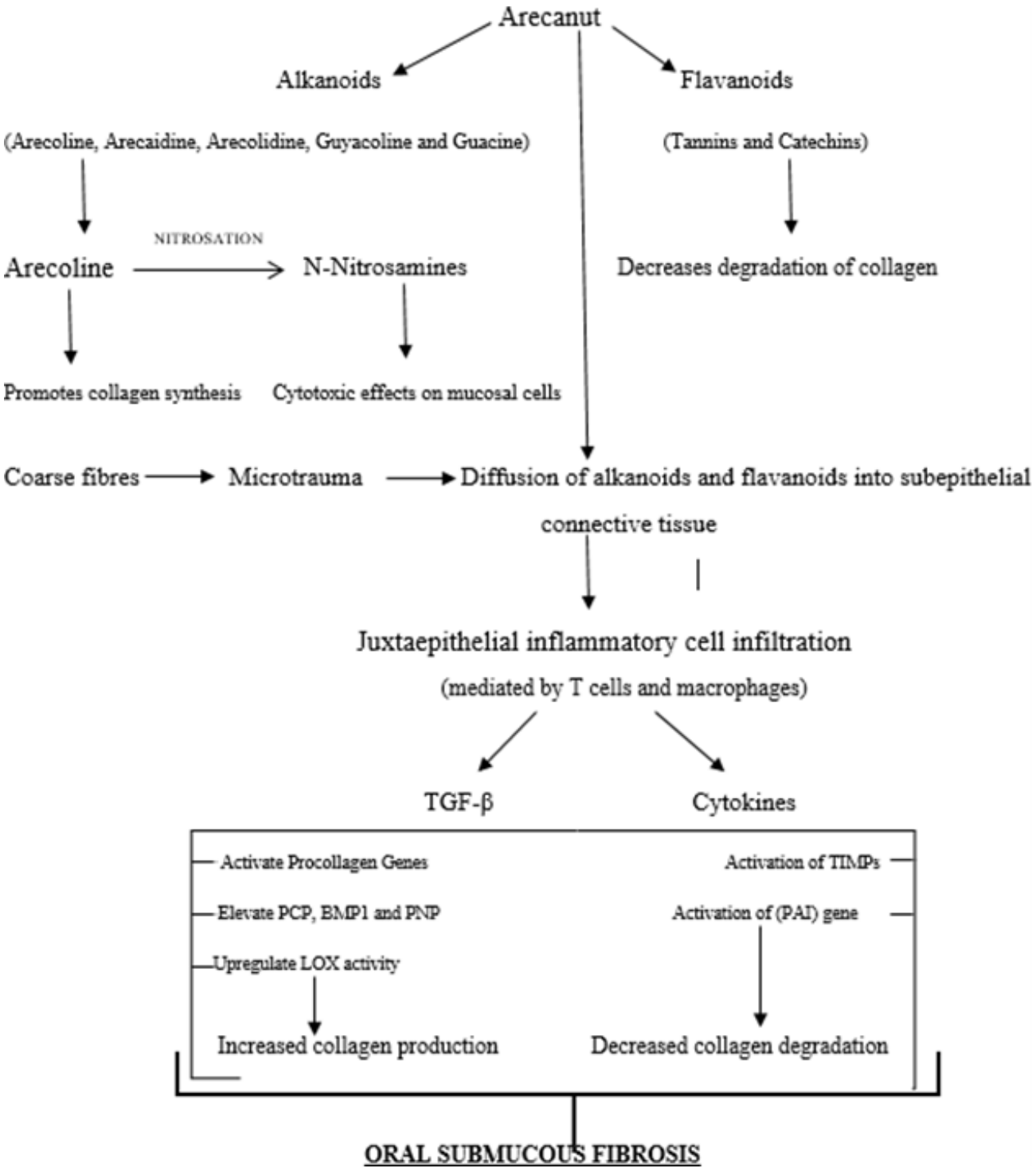
- Disease of Southeast Asia and Indian subcontinent
- Prevalence – 4.968
- Chewing arecanut

Annual malignant transformation rate 0.98% (Overall 5.2%)2

Clinical Features

- Burning sensation -consumption of spicy foodstuffs
- Blanching and stiffening of the oral mucosa and oropharynx
- Progressive inability to open mouth.
- Vesicles, ulcerations, or blanched oral mucosa.
- Petechiae – more common on palate.
- Increased salivation in early stages followed by xerostomia, change in taste sensation and dysphagia.
- Impaired jaw movements
- Hearing loss due to stenosis of Eustachian tubes.
- Nasal tone to speech

Etiopathogenesis



Classification of OSMF

Ranganathan et al classification (2001)

- **Group I**: Only clinical symptoms present with mucosal changes but no restriction of mouth opening (more than 35mm).
- **Group II**: Restricted mouth opening (between 20 to 35mm).
- **Group III**: Limited mouth opening (less than 20mm).
- **Group IV**: Nil mouth opening with precancerous or cancerous changes in oral mucosa.

Symptoms/ Signs	Burning sensation in the mouth, acute ulceration and recurrent stomatitis	Buccal mucosa mottled	Vertical fibrous bands at soft palate, pterygomandibular raphe and anterior faucial pillars	Thickened faucial pillars, shrunken uvula
Trismus/ Interincisal Distance	Absent >35 mm	Mild 26 to 35 mm	Moderate 15 to 25 mm	Severe <15 mm
Histopathology	Fine fibrillar collagen network, blood vessels dilated, inflammatory cells (PMN)	Juxta-epithelial hyalinization, thickened collagen bundles, keratinization	Juxta-epithelial hyalinization, constricted blood vessels, inflammatory cells (lymphocytes, plasma cells), epithelium atrophic	Extensive fibrosis, obliterated blood vessels, loss of epithelial rete pegs, atypia, degeneration of muscle fibers

Management[10]

Biopsy - Suspicious areas

Remove predisposing factor - Habit cessation, Nutritional build up

Medical: Intralesional injections - Hyaluronidase/ Steroids, Lycopene, Pentoxyphylline: **Do not work**

Surgical Management

Excision of fibrotic bands – Scalpel, laser

Mucosa reconstruction - Flaps, grafts, collagen membrane

Adjunctive procedures intraoperatively – Coronoidectomy, masticatory muscle myotomy

Post operative oral physiotherapy, dietary supplementation

Oral Lichen Planus

- A cell mediated immune condition of unknown etiology
- Predominantly in adult after age of 40 years.
- Commonly occurs on skin of genitalia, flexor surfaces of forearm, thigh, scalp, lips, oral-mucosa (buccal mucosa, tongue).
- A characteristic saw tooth appearance,band like lymphocyte infiltration at dermo-epidermal junction and degeneration of basal keratinocytes.

Clinical Features

- White striations
- White papules, white plaques, erythema
- Erosions or blisters affecting predominantly the buccal mucosa, tongue and gingivae.
- Flat-topped, pearly, pinkish-purple, pruritic, polygonal papules with peripheral fine milky white lace-like reticular pattern (Wickham's striae/Honiton lace)

Other Pre Malignant Oral Diseases

- Actinic cheilitis.
- Ulcerative crust forming lesion involving lower lip, vermillion border.
- Inherited cancer syndrome
- Xerodermapigmentosum, Fanconi's anemia.
- Immunodeficiency.
- Palatal lesion in reverse smokers.

Treatment
Not all Lesions Require Invasive Management

- **High risk features -**
  - Surgery
  - Medical management
  - Surgery + medical

- **Low risk group –**
  - Observe
  - Regular follow up
  - Habit cessation

Surgical Management

- Excision of lesion with clear margins
- Recurrence rate following surgery - 15- 55 %
  -Schoelch 1999, Pandey 2000
  -Vedtofte 1987, Subde 2004
- No randomised trial comparing surgery vs observation

Surgery Issues

- Diffuse large lesion
- Radical surgery with cosmetically unacceptable outcomes
- Unwillingness by patient
- High recurrence rate despite complete removal & negative margins

Chemoprevention

- **Primary chemoprevention:** Prevention of cancer development in healthy population
- **Secondary chemoprevention:** Prevention of progression of pre-malignant lesions into cancers
- **Tertiary chemoprevention:** Prevention of new cancer development in cured cancer patients or treated pre-malignant lesions

Conclusions

- Adverse effects common but good compliance
- High relapse rate on stoppage of treatment
- Need for further trials with new agents exist
- PMD with high risk features should be treated
- Homogenous lesions, low risk features may be observed
- Long term follow up is needed despite treatment as relapse is common
- Existing chemopreventive agents are not effective
- No evidence to practice chemoprevention in routine practice

CHAPTER 6

"PREVENTION IS BETTER THAN CURE"
OVERVIEW OF STAGING AND MANAGEMENT OF ORAL CANCER

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Staging:
Primary Tumour

TX Primary tumor cannot be assessed

Tis Carcinoma in situ

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* ≤10 mm

T3 Tumor >2 cm and ≤4 cm, 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 >4 cm, with DOI* >10 mm or tumor invades adjacent structures only (eg, 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.

Regional Node

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 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, and ENE(–)

N2a Metastasis in a single ipsilateral lymph node larger than 3 cm but not larger than 6 cm in greatest dimension, and ENE(–)

N2b Metastases in multiple ipsilateral lymph 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 Matastasis in a lymph node larger than 6 cm in greater dimension and ENE(-) or metastasis in any node(s) and clinically overt ENE(+).

N3a Metastasis in lymph node larger than 6 cm in greatest dimension and ENE(-).

N3b Metastasis in any node(s) and clinically overt ENE(+).

Distant Metastasis

M0 No distant metastasis

M1 Distant metastasis

Treatment Management

LIP:

- Early Lesion (T1-2N0): Surgery / Radiation (Single Modality)
- If patient undergoes surgery, then:
- Post-op RT indication:

1. Close Margin
2. PNI/LVSI (+)

- Post-op CTRT Indication:

Positive Margin.

- If patient receives Radiation, then its generally preferred for lesions involving commissure, 2cm lesion, upper lip lesion.
- Radiation options: EBRT / Brachytherapy / Electrons.
- Salvage Surgery for residual disease after radiation.
- Advanced Lesion (T3-4a or N1-3): Multimodality treatment
- Preferred Surgery:-
- Post-op RT Indication: All patients
- Post-op CTRT Indication: ECE / Positive Margin
- If patient receives Chemoradiation +/- Brachytherapy, then for primary tumor <CR go for salvage surgery and neck dissection.
- If residual neck involvement by imaging at 6-12weeks, consider salvage neck dissection.

Oral Cavity

- T1-2N0:
- Preferred: Surgical resection of primary with ipsilateral or bilateral selective neck dissection (consider B/L for midline, oral tongue, or FOM), Neck treatment (Dissection or RT) for lesion >2-3mm thick. For positive margin only, re-excise if feasible.
- Post-op RT alone (including neck if not dissected) indicated for close margin (<5mm), PNI or LVSI. Post-op CTRT for positive margin.

Alternatively: Definitive EBRT +/- Brachytherapy. Salvage surgery for residual disease.

- T3-4a or N1-3:
- Preferred: Surgical resection of primary with I/L or B/L selective Neck dissection (Consider B/L for tumor approaching midline, oral tongue, FOM, N2c). Reconstruction as indicated.
- Post-op RT for all & Post-op CTRT for Positive margin or ECE.
- Unresectable tumor:
- Preferred-Concurrent CTRT with cisplatin-based regimen.
- Alternative: Induction chemotherapy followed by CTRT or Altered fractionation RT if unable to tolerate chemo.

Primary tumor <CR go for salvage surgery controversial. If residual neck involvement by imaging at 6-12weeks, consider salvage neck dissection.

Role of chemotherapy along with RT

- Randomized trial and meta-Analysis showed significantly improved OS, DFS, and locoregional control when a systemic therapy and RT regimen (concomitant or, less commonly, sequential) was compared with RT alone for locally advanced disease. Limited data available on comparing different chemoradiotherapy regimen.
- A randomized phase III trial comparing 3 weekly cisplatin vs weekly cisplatin both given with RT to locally advanced SCCHCN. The primary end point was locoregional control.
- 2year locoregional control rate 58.5% in weekly arm and 73.1% in 3weekly arm.
- Acute toxicity of Grade 3 or more was less in weekly compared to 3weekly arm (71.6% vs 84.6%).

- Phase III randomized trial RTOG 0522 showed that addition of cetuximab to cisplatin and RT did not significantly improve OS, compared to cisplatin and RT, in patients with stage III or IV SCCHN and, importantly, was more toxic.
- Phase III GORTEC 2007-01 trial, cetuximab combined with carboplatin / 5FU and RT was compared to cetuximab and RT. 3Year PFS (52.3% vs 40.5%), respectively; and locoregional failure (21.6% vs 38.8%) rates were better with combination regimen, but OS and distant metastasis rates were not significantly improved.
- Grade 3 or 4 mucositis and hospitalization for toxicity were more prevalent in patients who received cetuximab combined with carboplatin/5FU and RT.
- Cetuximab combined with chemoradiation is not recommended as treatment for SCCHN.

Induction Chemotherapy

- No survival advantage to induction chemotherapy before chemoradiation, in part due to toxicity and inability to complete chemoradiation. Slight advantage in distant metastasis. Three agent regimens containing taxanes are superior.
- Possible scenarios for induction chemotherapy unavoidable delays in starting chemoradiation, markedly advanced disease, oligometastasis, or very high metastatic potential.
- Studies:
- TAX 324 (Posner et al):-
- Randomized to TPF vs PF Induction chemotherapy.
- TPF Improved median PFS (13 – 38 months) and OS (35-71 months).
- More acute hematological toxicity with TPF, but more delays with PF. No significant difference in late Toxicity.
- Other studies: PARADIGM (Haddad et al).

Principles of Systemic Therapy

- Choice of systemic therapy should be individualized based on patient characteristics (e.g., PS, goals of therapy).
- The preferred chemoradiotherapy approach for fit patients with LAHNSCC remains concurrent cisplatin and radiotherapy.
- Cisplatin based induction chemotherapy can be used, followed by radiation based locoregional treatment (ie, sequential chemoRT).
- However, an improvement in overall survival with incorporation of induction chemotherapy compared to proceeding directly to concurrent CTRT has not been established in randomized studies.
- Cisplatin based induction chemo followed by 3weekly cisplatin chemoradiation is associated with toxicity concerns.
- After induction chemo, multiple options can be used for the radiation-based portion of therapy, including radiation alone, particularly for patients with complete response after induction chemotherapy.

Radiation Techniques

- Simulate supine with neck extended, shoulder retraction. Immobilize with thermoplastic head & neck mask. Wire scars. Cork and tongue blade to depress tongue from palate if appropriate.
- CT Planning with fusion to MRI, Contrast-enhanced CT, and/or PET-CT.
- IMRT Volumes Post op case:
- GTV= Clinical or radiographic gross disease, if present (primary and nodes).
- CTV1=Entire postop bed, including >/0.5-2cm margin on GTV (Depending on anatomic boundaries to microscopic spread), and areas of close/positive margins, ECE. Entire flap is covered if reconstructed.
- CTV2=Elective Neck (Dissected neck, high risk cN0, contralateral neck).
- PTV=CTV + 3-5mm (Depending on tumor motion & set-up Error).

LIP

- T1-2 may be treated with EBRT(100-250 KV photons or 6-12MeV electrons), with brachytherapy or both.
- Appositional field for EBRT. Borders determined clinically with 1-1.5cm margin for orthovoltage or 2-2.5cm margin for electrons. Bolus for superficial tumors. Wax coated lead shield behind lip to reduce dose to mandible and oral cavity.
- Brachytherapy alone (<2cm):- 45Gy/15# HDR.
- Electron beam:- 60-70Gy/6-7 weeks.
- EBRT:- 50Gy/25# followed by brachytherapy 15-20Gy/5-7#.

Oral Cavity

- Low RT tolerance due to increased risk of soft tissue injury and osteoradionecrosis.
- Use cork & tongue blade to depress tongue from palate. Need secure setup due to tongue mobility.
- For superficial T1-2 lesions, brachytherapy or intraoral cone RT may be in lieu of surgery.
- LDR brachytherapy dose 60-70Gy. Intraoral cone RT dose is 3Gy x 15-20#.
- For definitive treatment of larger lesions, 3DCRT or IMRT techniques are generally recommended for advanced lesions in order to spare adjacent normal structures. EBRT:- 50Gy/25# followed by brachytherapy 15-20Gy/5-7#.
- Suggested Nodal coverage (all B/L): Level I-IV, include Level V for (+)LN.

Gingiva, Hard Palate, & Retromolar Trigone:

- Brachytherapy is generally avoided due to risk of osteoradionecrosis.
- For Gingival tumors, if PNI (+) the entire hemimandible from mental foramen to TMJ is included.
- MRI can help identify perineural spread along major nerves (e.g., Inferior alveolar nerve). If radiographically or clinically involved, or extensive PNI present, cover nerve pathway at least to the base of skull foramina and consider covering to trigeminal ganglion.
- Suggested Nodal coverage:
- T1-4N0: I/L Levels I-IV if well lateralized, otherwise consider covering C/L neck.
- LN(+): I/L Levels I-V, Consider C/L Neck.

CHAPTER 7

SIDE-EFFECTS OF RADIATION AND CHEMOTHERAPY AND THEIR MANAGEMENT – DO'S & DON'T'S

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What are Indications of Radiation Therapy?

About 2/3 of all cancer patients needs Radiation therapy as part of their treatment

1. **PALLIATIVE RT:** Brain Mets, Bone Mets, Cord compression, etc.
2. **PROPHYLACTIC RT:** ALL, SCLC
3. **REIRRADIATION:** Recurrences in treated RT field

The **goal of radiation therapy** is to destroy **cancer** cells and slow tumor growth while limiting the harm to nearby normal, healthy cells.

Types of Side Effects

- **Acute:** The early or acute effects occur in tissues with rapid cell renewal, in which cell division is required to maintain the tissue function of the organ.
- **Late:** Late reacting normal tissue shows their response over month or year after irradiation. It occurs in slowly proliferating tissues such as lung, kidney, heart, liver and spinal cord.

H & N	Grade 1	2	3	4
Skin	Follicular, faint or dull erythema / epilation / dry desquamation / decreased sweating	Tender or bright erythema, patchy moist desquamation / moderate edema	Confluent, moist desquamation other than skin folds, pitting edema	Ulceration, hemorrhage, necrosis
Mucous Membrane	Irritation / may experience mild pain not requiring analgesic	Patchy mucositis that may produce an inflammatory serosanguinous discharge / may experience moderate pain requiring analgesia	Confluent fibrinous mucositis / may include severe pain requiring narcotic	Ulceration, hemorrhage or necrosis

H & N	Grade 1	2	3	4
Skin	Follicular, faint or dull erythema / epilation / dry desquamation / decreased sweating	Tender or bright erythema, patchy moist desquamation / moderate edema	Confluent, moist desquamation other than skin folds, pitting edema	Ulceration, hemorrhage, necrosis
Mucous Membrane	Irritation / may experience mild pain not requiring analgesic	Patchy mucositis that may produce an inflammatory serosanguinous discharge / may experience moderate pain requiring analgesia	Confluent fibrinous mucositis / may include severe pain requiring narcotic	Ulceration, hemorrhage or necrosis
Eye	Mild conjunctivitis w/ or w/o scleral injection / increased tearing	Moderate conjunctivitis w/ or w/o keratitis requiring steroids and/or antibiotics / dry eye requiring artificial tears / iritis with photophobia	Severe keratitis with corneal ulceration / objective decrease in visual acuity or in visual fields / acute glaucoma / panophthalmitis	Loss of vision (uni or bilateral)
Ear	Mild external otitis with erythema, pruritus, secondary to dry desquamation not requiring medication. Audiogram unchanged from baseline	Moderate external otitis requiring topical medication / serous otitis media / hypoacusis on testing only	Severe external otitis with discharge or moist desquamation / symptomatic hypoacusis / tinnitus, not drug related	Deafness
Salivary Gland	Mild mouth dryness / slightly thickened saliva / may have slightly altered taste such as metallic taste / these changes not reflected in alteration in baseline feeding behavior, such as increased use of liquids with meals	Moderate to complete dryness / thick, sticky saliva / markedly altered taste	(none)	Acute salivary gland necrosis
	1	**2**	**3**	**4**
Pharynx/ Esophagus	Mild dysphagia or odynophagia / may require topical anesthetic or non-narcotic analgesics / may require soft diet	Moderate dysphagia or odynophagia / may require narcotic analgesics / may require puree or liquid diet	Severe dysphagia or odynophagia with dehydration or weight loss > 15% from pretreatment baseline requiring NG feeding tube, IV fluids, or hyperalimentation	Complete obstruction, ulceration, perforation, fistula

H & N	Grade 1	2	3	4
Larynx	Mild or intermittent hoarseness / cough not requiring antitussive / erythema of mucosa	Persistent hoarseness but able to vocalize / referred ear pain, sore throat, patchy fibrinous exudate or mild arytenoid edema not requiring narcotic / cough requiring antitussive	Whispered speech, throat pain or referred ear pain requiring narcotic / confluent fibrinous exudate, marked arytenoid edema	Marked dyspnea, stridor or hemoptysis with tracheostomy or intubation necessary
Lungs	Mild symptoms of dry cough or dyspnea on exertion	Persistent cough requiring narcotic, antitussive agents / dyspnea with minimal effort but not at rest	Severe cough unresponsive to narcotic antitussive agent or dyspnea at rest / clinical or radiological evidence of acute pneumonitis / intermittent oxygen or steroids may be required	Severe respiratory insufficiency / continuous oxygen or assisted ventilation
Heart	Asymptomatic but objective evidence of EKG changes or pericardial abnormalities without evidence of other heart disease	Symptomatic with EKG changes and radiological findings of congestive heart failure or pericardial disease / no specific treatment required	Congestive heart failure, angina pectoris, pericardial disease responding to therapy	Congestive heart failure, angina pectoris, pericardial disease, arrhythmias not responsive to nonsurgical measures
	1	**2**	**3**	**4**
Upper GI	Anorexia with ≤ 5% weight loss from pre treatment baseline / nausea not requiring antiemetics / abdominal discomfort not requiring parasympatholytic drugs or analgesics	Anorexia with ≤ 15% weight loss from pretreatment baseline / nausea and/or vomiting requiring antiemetics / abdominal pain requiring analgesics	Anorexia with > 15% weight loss from pre treatment baseline or requiring NG tube or parenteral support. Nausea and/or vomiting requiring tube or parenteral support / abdominal pain, severe despite medication / hematemesis or melena / abdominal distention (flat plate radiograph demonstrates distended bowel loops)	Ileus, subacute or acute obstruction, perforation, GI bleeding requiring transfusion / abdominal pain requiring tube decompression or bowel diversion

H & N	Grade 1	2	3	4
Lower Gi/pelvis	Increased frequency or change in quality of bowel habits not requiring medication / rectal discomfort not requiring analgesics	Diarrhoea requiring parasympatholytic drugs (e.g. Lomotil) / mucous discharge not necessitating sanitary pads / rectal or abdominal pain requiring analgesics	Diarrhoea requiring parenteral support / severe mucous or blood discharge necessitating sanitary pads / abdominal distention (flat plate radiograph demonstrates distended bowel loops)	Acute or subacute obstruction, fistula or perforation; GI bleeding requiring transfusion; abdominal pain or tenesmus requiring tube decompression or bowel diversion
Genitourinar	Frequency of urination or nocturia twice pretreatment habit / dysuria, urgency not requiring medication	Frequency of urination or nocturia that is less frequent than every hour. Dysuria, urgency, bladder spasm requiring local anesthetic (e.g. Pyridium)	Frequency with urgency and nocturia hourly or more frequently / dysuria, pelvis pain or bladder spasm requiring regular, frequent narcotic / gross hematuria with/without clot passage	Hematuria requiring transfusion / acute bladder obstruction not secondary to clot passage, ulceration, or necrosis
CNS/ HEME	**1**	**2**	**3**	**4**
CNS	Fully functional status (i.e. able to work) with minor neurological findings, no medication needed	Neurological findings present sufficient to require home care / nursing assistance may be required / medications including steroids/antiseizure agents may be required	Neurological findings requiring hospitalization for initial management	Serious neurological impairment that includes paralysis, coma, or seizures > 3 per week despite medication / hospitalization required
WBC	3.0 - < 4.0	2.0 - < 3.0	1.0 - < 2.0	< 1.0
Platelet	75 - < 100	50 - < 75	25 - < 50	<25 or spontaneous bleeding
Neutrophils	1.5 - < 1.9	1.0 - < 1.5	0.5 - < 1.0	< 0.5 or sepsis
Hgb/Hct	11 - 9.5 (28% - < 32%)	< 9.5 - 7.5 (< 28%)	< 7.5 - 5.0 (Packed cell transfusion required)	(none)

RTOG/EORTC Late Radiation Morbidity

Tissue	Grade 1	2	3	4
Skin	Slight atrophy; pigmentation change; some hair loss	Patch atrophy; moderate telangiectasia; total hair loss	Marked atrophy; gross telangiectasia	Ulceration
Subcutaneous tissue	Slight induration (fibrosis) and loss of subcutaneous fat	Moderate fibrosis but asymptomatic; slight field contracture; <10% linear reduction	Severe induration and loss of subcutaneous tissue; field contracture > 10% linear measurement	Necrosis
Mucous membrane	Slight atrophy and dryness	Moderate atrophy and telangiectasia; little mucous	Marked atrophy with complete dryness	Ulceration
Salivary glands	Slight dryness of mouth; good response on stimulation	Moderate dryness of mouth; poor response on stimulation	Complete dryness of mouth; no response on stimulation	Fibrosis
Spinal cord	Mild L'Hermitte's syndrome	Severe L'Hermitte's syndrome	Objective neurological findings at or below cord level treated	Mono, para quadriplegia
Brain	Mild headache; slight lethargy	Moderate headache; great lethargy	Severe headache; severe CNS dysfunction (partial loss of power or dyskinesia)	Coma
Eye	Asymptomatic cataract; minor corneal ulceration or keratitis	Symptomatic cataract; moderate corneal ulceration; minor retinopathy or glaucoma	Severe keratitis; severe retinopathy or detachment	Panophthalmitis / blindness
Larynx	Hoarseness; slight arytenoid edema	Moderate arytenoid edema; chondritis	Severe edema; severe chondritis	Necrosis
Lung	Asymptomatic or mild symptoms (dry cough); slight radiographic appearances	Moderate symptomatic fibrosis or pneumonitis (severe cough); low grade fever; patchy radiographic appearances	Severe symptomatic fibrosis or pneumonitis; dense radiographic changes	Severe respiratory insufficiency / Continuous oxygen / assisted ventilation
Heart	Asymptomatic or mild symptoms; transient T wave inversion & ST changes; sinus tachy> 110 (at rest)	Moderate angina on effort; mild pericarditis; normal heart size; persistent abnormal T wave and ST changes; low ORS	Severe angina; pericardial effusion; constrictive pericarditis; moderate heart failure; cardiac enlargement; EKG abnormalities	Tamponade / severe heart failure; severe constrictive pericarditis

Tissue	Grade 1	2	3	4
Esophagus	Mild fibrosis; slight difficulty in swallowing solids; no pain on swallowing	Unable to take solid food normally; swallowing semisolid food; dilatation may be indicated	Severe fibrosis; able to swallow only liquids; may have pain on swallowing; dilatation required	Necrosis / perforation fistula
Small/Large intestine	Mild diarrhea; mild cramping; bowel movement 5 times daily; slight rectal discharge or bleeding	Moderate diarrhea and colic; bowel movement > 5 times daily; excessive rectal mucus or intermittent bleeding	Obstruction or bleeding, requiring surgery	Necrosis / perforation fistula
Liver	Mild lassitude; nausea, dyspepsia; slightly abnormal liver function	Moderate symptoms; some abnormal liver function tests; serum albumin normal	Disabling hepatic insufficiency; liver function tests grossly abnormal; low albumin; edema or ascites	Necrosis / hepatic coma or encephalopathy
Kidney	Transient albuminuria; no hypertension; mild impairment of renal function; urea 25-35 mg/dL; creatinine 1.5-2.0 mg/dL; creatinine clearance > 75%	Persistent moderate albuminuria (2+); mild hypertension; no related anemia; moderate impairment of renal function; urea > 36-60; creatinine clearance 50-74%	Severe albuminuria; severe hypertension; persistent anemia (< 10); severe renal failure; urea > 60; creatinine > 4.0; creatinine clearance < 50%	Malignant hypertension; uremic coma; urea > 100
Bladder	Slight epithelial atrophy; minor telangiectasia (microscopic hematuria)	Moderate frequency; generalized telangiectasia; intermittent macroscopic hematuria	Severe frequency & dysuria; severe telangiectasia (often with petechiae); frequent hematuria; reduction in bladder capacity (<150 cc)	Necrosis/contracted bladder (capacity < 100 cc); severe hemorrhagic cystitis
Bone	Asymptomatic; no growth retardation; reduced bone density	Moderate pain or tenderness; growth retardation; irregular bone sclerosis	Severe pain or tenderness; complete arrest of bone growth; dense bone sclerosis	Necrosis / spontaneous fracture
Joint	Mild joint stiffness; slight limitation of movement	Moderate stiffness; intermittent or moderate joint pain; moderate limitation of movement	Severe joint stiffness; pain with severe limitation of movement	Necrosis / complete fixation

Some General Side Effects Are:

1. SKIN

- Dry desquamation
- Moist desquamation

Dry Desquamation

Intervention:

- Only loose-fitting cotton clothing should be worn.
- Avoid using adhesive tape over the irradiated skin.

If the skin becomes dry and complain of tenderness and pruritis-

- A hydrophilic moisturizing lotion may be applied.
- Topical steroids can help decrease pruritis& tenderness because of vasoconstriction (SHOULD NOT BE RECOMMENDED FOR MOIST DESQUAMATION).

Moist Desquamation

Intervention

Normal saline irrigations or cool compresses may be applied.

- Silver sulfadiazine
- Hydrocolloid cream dressing

Stomatitis

Intervention

- If tooth brushing becomes too painful, lukewarm saline rinses and gentle swabbing with moistened gauze.
- Poorly fitting dental prosthesis should not be worn.
- Oral pain with topical anaesthetics or systemic analgesics.
- soft blend diet to make chewing and swallowing easier.

Xerostomia

Intervention

Assist the patient and family to proper diet.
Emollients for cracked lips.
saliva substitutes provide temporary relief of xerostomia.
Frequent sips of fluid, sucking on sugarless sour candies can help stimulate salivation.

Osteoradionecrosis:
A late and chronic effect of RT,
usually occurs in the mandible.

Intervention

- good oral hygiene guidance.
- Frequent visit to dentist for evaluation.
- Minimizing mouth irritants such as tobacco, alcohol as well as evaluating fit and comfort of dentures.

Nausea & Vomitting

Intervention

- Assess patients for occurrence of nausea and vomiting.
- Prophylactic use of antiemetics before treatment each day.
- A diet low in fat, low in sugar and easily digested are best tolerated.
- Evaluate patient's and family's understanding of the potential and actual causes of nausea and vomiting.
- Also evaluate their ability to use appropriate measures to reduce or relieve nausea and vomiting.

Diarrhoea

Diarrhoea commonly occur when the pelvis is being treated for gynaecologic cancer, prostate cancer, testicular cancer, rectal cancer or lymphomas.

Intervention:

- Assess patient's usual bowel pattern.
- If diarrhoea occurs, help the patient and family plan measures to minimize diarrhoea.
- Instruct the patient and family to use low residue diet.
- Decrease the amount of fat.
- Milk products should be avoided if not tolerated.
- If diarrhoea persists while the patient is on low residue diet, antidiarrheals may be indicated like loperamide HCl.
- Evaluate their level of understanding.

Cystitis:

Intervention:

- Assess and monitor symptoms of cystitis, including signs of haematuria
- Instruct the patient to maintain adequate fluid intake
- Bladder infections must be ruled out or treated.
- Obtain urine sample for routine analysis and culture.
- Bladder analgesics such as phenazopyridine.
- Antispasmodic can provide some relief from bladder spasm
- Evaluate their understanding of the causes of cystitis and ways to relieve symptoms.

Erectile Dysfunction

It may result as a result of fibrosis of the pelvic vasculature and damage of pelvic nerves.

Intervention:

- Allow the patient and his partner to discuss concerns and feelings regarding changes in sexual functioning and body image
- Consultation with an Radiation Oncologist/Urologist

Vaginal Stenosis

Intervention:

- Vaginal stenosis may develop and cause dyspareunia and difficulties with pelvic examination.
- Well lubricated vaginal dilation can be done for at least 1year 3 times a week.

Common Chemotherapy Side Effects

- Tiredness (Fatigue)
- Nausea & Vomiting
- Loss of appetite
- Diarrhea & Constipation
- Alopecia
- Skin and nail changes
- Bone marrow suppression – Anemia, Leukopenia, Thrombocytopenia
- Sex and fertility issues

Fatigue

Intervention:

Assess and evaluate for presence, pattern & factors of fatigue.

Referring to a dietician helps to plan the patient's nutritional program.

Anorexia

Intervention

- Assess the loss of appetite in patients and importance of nutrition during therapy.
- Frequent small meals rather than three large ones.
- Nutritional supplements and convenience foods can provide additional calories and protein.

Bone Marrow Suppression

- Anemia
- Neutropenia
- Thrombocytopenia

Aloplecia

Intervention

- Prepare patient and family in advance for alopecia.
- Approaching the patient with gentleness, honesty and caring, and allowing verbalisation of fears, grief and anger.
- A mild shampoo should be, excessive shampooing should be avoided.
- Gentle brushing and combing is recommended.
- Hair colouring are contraindicated.

When to get urgent medical advice after chemotherapy

- A temperature of above 37.5C or below 36C
- Your skin feels warm to touch, or you feel hot and shivery
- Breathing difficulties
- Flu-like symptoms, such as muscle aches and pain
- A sore mouth
- Pain when swallowing
- Being sick
- Diarrhoea
- Pain, swelling, redness, heat and /or a discharge of liquid at the site of a wound (such as a surgical scar) or where an intravenous or catheter line has been put into one of your veins (usually your upper arm)

CHAPTER 8

TOBACCO CESSATION

Dr. Arundhati Deka
State Nodal Officer -National Tobacco Control Programme, Assam

National Tobacco Control Programme, Assam

The quitting process involves three steps :

- A. Preparation before quitting;
- B. Actual quitting;
- C. Life after Quitting.

Decide to Quit and Get Ready to Stop

1.First, Ask Yourself Why:-

List all the reasons why you continue using Tobacco.

List all the reasons why you want to stop Tobacco

2.Know your Habit.

3. Set a quit Date: Take a Oath (If I smoke, some thing bad will happen)

4.Choose a method :--

Tapering off S-L-O-W-L-Y

Before the quit date : Make Changes (clean up, change tobacco time & place, grab more sleep, try eating ground nuts & chewing gum)

6.Tell the friends that you are quitting

7. Rewards yourself when you can arrive STOP date.

Every year, 60-70% Tobacco users want to quit, only 20% try, only 2-3% succeed by themselve, it is because of Nicotine is so addictive so using of MEDICINE is additional for success of quitting.

- NRT decreases the withdrawal symptoms & improves chances of stopping tobacco usages. NRT is a form of product containing N that replaces N receive from tobacco . NRT as Gums & Patches
- Gums:N gums are used for at least 4 weeks. Gums are 2mg & 4mg. Gums can be used for both smokers and chewers.
- Patches:
- Pills : Bupropion is a non –N treatment . It reduces the craving &withdrawl symptoms. Varfenciline, Nortryptiline, Selegeline, Clonidine etc
- On Quit day – should Keep busy , remind family , friends and co-workers, deep breathing, keep some things in mouth.
- Craving will be more in 1stweek , it last for 30-90 sec. Remember craving is temporary.
- Three R s : Remind, Rehearse , Reward yourself.

Coping With Withdrawal:

Withdrawal is good news. That means flushing out harmful effect of tobacco chemicals. Withdrawal CAN CAUSE – difficult in concentrating, Insomnia, irritability, anger, frustrations

Life After Stopping:

- Refuse offers of Tobacco
- Challenging negative thought
- Try new ways to relax: Deepbreathing,Relaxation Through mind, through activity,Yoga,drinking non-alcoholic beverages.

What Difference will Quitting Make

- After 20 minutes:-**1**. Blood pressure & pulse rate become normal. **2**. Body temperature of hands & feet increases to normal
- After 8 Hrs:- 1. CO in body drops. 2.Oxygen in blood increases to normal.
- After 2 days:-1. Sense of smell & taste improves.2. Risk of heart attack begins to decrease.
- After 3-4 days:- Bronchial tubes relax & lung capacity will have increased, making breathing easier.
- After 2 weeks:- Blood flow improves, N – passed from body.
- Within 2 weeks to 3 months: - Circulation will improve, making walking and running easier, Lung function increase upto 30%.
- Within 6-9 months:-Less coughing, sinus, congestion,tiredness, shortness of breathing.
- After 1 Year: Risk of heart disease will be reduced to half.
- After 5 Years: Risk of strokes substantially reduces.
- After 10 years: Risk of dying from lung cancer will be half.
- Risk of cancer of the mouth , throat , oesophagus, bladder, kidney, pancreas will decrease.
- Within 15 years Risk of dying from a heart attack is equal to a person who never smoked.
- Other Benefit: Self image and self confidence will improve. One will feel proud of your ability to overcome something so challenging. One will have more energy to do the things one love to do.

Tobacco Control
Tobacco Control Act, 2003

Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution)Act,2003 (COTPA)

PROVISIONS OF THE ACT

- **Prohibition of smoking in public places (Section 4)**
- **Prohibition of advertisement, sponsorship and promotion of tobacco products (Section 5)**
- **Prohibition of sale of tobacco products to minors (Section 6 - a)**
- **Prohibition of sale of tobacco products near educational institutions(Section6 – b)**
- **Display of pictorial health warning on tobacco products packs (Section 7)**

Section 4

Smoking in all "public places" is prohibited: Any violation of this act is a punishable offence with fine up to **Rs. 200.**

- **"Public Place" means any place to which the public has access whether as of right or not and includes all places visited by general public. It includes:**
- **Offices**
- **Auditorium**
- **Hospital Buildings**
- **Health Institutions**
- **Amusement Centers**
- **Restaurants**
- **Hotels, Restaurants**
- **Public Offices**
- **Court Buildings**
- **Educational Institutions**
- **Libraries**
- **Public Conveyances**
- **Open Auditorium, Bus stop**
- **Open Railway station**
- **Stadium**
- **Railway Stations**
- **Bus Stops**
- **Workplaces**
- **Shopping Malls**
- **Cinema Halls**
- **Refreshment Rooms**
- **Discotheques**
- **Coffee House**
- **Pubs**
- **Bars**
- **Airport Lounge and**
- **Prisons**
- **Prohibition of smoking in a public place**
- (1) The owner, proprietor, manager, supervisor or in charge of the affairs of a public place shall ensure that:
- **(a) No person smokes in the public place.**
- (b) The board as specified is displayed prominently
- (c) No ashtrays, matches, lighters or other things designed to facilitate smoking are provided in the public place.
- (2) The owner shall notify and display prominently the name of the person to whom a complaint may be made by any person who observes another person smoke in no smoking premises.
- (3) The owner, proprietor, manager, supervisor or in-charge of a **hotel, having thirty or more rooms or restaurant having seating capacity of thirty persons or more and the manager of the airport** may provide for a smoking area or space. Such smoking area or space shall not be established at the entrance or exit and shall be distinctively marked as **"Smoking Area"** in English or one Indian language, as applicable.
- A smoking area or space, shall be used only for the purpose of smoking and no other service(s) shall be allowed as applicable.

be prominent, legible and in black colour with white background.

The board shall only list the type of tobacco product available and *no brand pack shot, brand name of tobacco product or any promotional message or picture.* The display shall not be back lit or illuminated in any manner.

Section 6

- Sale of tobacco products **to and by** persons under the age of 18 years is prohibited.
- The seller should ensure that the person who is buying the tobacco product is not a minor.
- A **display board** to be put up at the point of sale declaring that **'sale of tobacco products to a person below the age of 18 is a punishable offence' with a pictorial depiction.**
- **Section 6 (b)**
- In order to restrict access of tobacco products to youth, the sale of the same is prohibited in an area within radius of 100 yards of any educational institutions.
- A display board to be put up outside the educational institutions declaring the same.
- Sale of tobacco products **to and by** persons under the age of 18 years is prohibited.
- The seller should ensure that the person who is buying the tobacco product is not a minor.
- A display board to be put up at the point of sale declaring that 'sale of tobacco products to a person below the age of 18 is a punishable offence' with a pictorial depiction.
- **Section 6 (b)**
- In order to restrict access of tobacco products to youth, the sale of the same is prohibited in an area within radius of 100 yards of any educational institutions.
- A display board to be put up outside the educational institutions declaring the same.

Section 7

Display of pictorial health warnings on all tobacco product packs

Penalties for Violation of COTPA

Section of COTPA	Penalties
Section 4: Prohibition of Smoking in a Public Place	**a)** To the individual offender: up to Rs. 200/- **b)** To owner, manager or authorised officer: Fine equivalent to member of offences in public Place.
Section 5: Prohibition of advertisement of Cigarette and other tobacco products	**a)** 1st offence: 2 Years/ Rs.1000/- **b)** 2nd offence: 5 Years/ Rs. 5000/-
Section 6: Prohibition on sale to minors and around educational institutes	**a)** Up to Rs. 200/-
Section7,8. & 9: Prohibition on sale of Cigarette and other tobacco products without specified health warning	**a) Manufacturers:** 1st offence: 2 Years/ Rs.5000/- 2nd offence: 5 Years/ Rs. 10,000/- **b) Selling/Retailing:** 1st offence: 1 Year/ Rs.1000/- 2nd offence: 2 Years/ Rs. 3000/-

Summary

Several other legislations have been used in India to strengthen tobacco control. Provisions of Food Safety Law, Juvenile Justice Act, Motor Vehicle Act, Environment Protection Act etc. besides local and municipal legislations have been extensively used to advance tobacco control in the country.

- **The Plastic Waste Management(Amendment) Rules, 2016**
- Rule 4 (f) mandates: Sachets using plastic material shall not be used for storing, packing or selling gutka, tobacco and pan masala.
- Rule 4 (i) of the said Rules, mandates: plastic material in any form including Vinyl Acetate, Maleic Acid, and Vinyl Chloride Copolymer, shall not be used in any package for packaging gutka, pan masala and tobacco in all forms.

Drug & Cosmetic Act

(i) The Central Government vide notification GSR 443(E), dated 30th April, 1992, under Section 33(EED) of the Drugs and Cosmetics Act, 1940 and Notification GSR 444(E), dated 30th April, 1992, under Section 26A of the Drugs and Cosmetics Act, 1940, prohibited the use of tobacco in tooth-pastes/tooth-powders.

(ii) The sale, supply, import, manufacturing and trade of nicotine for human consumption in India is only permitted under "Schedule K" of "Drugs and Cosmetic Rules, 1945" at item No.33 wherein 2mg or 4mg of nicotine in Chewing Gums/Lozenges is permitted as an aid for nicotine replacement therapy (NRT).

(iii) Section 18© of the Drugs and Cosmetics Act, 1940, states, no person shall himself or by any other person on his behalf, manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug, except under, and in accordance with the conditions of, a license issued for such purpose.

The Juvenile Justice (Care and Protection of Children) Act, 2015 No. 2 of 2016

• Under Section 77 of the Act **it is an offences against a child, if a person gives or causes to be given,** to any child any intoxicating liquor or any narcotic drug **or tobacco products** or psychotropic substance, except on the order of a duly qualified medical practitioner, shall be punishable with **rigorous imprisonment for a term which may extend to seven years** and shall also be liable to a fine which may extend up to **one lakh rupees.**

Enforcement Officer: Child Welfare Police Officer" which are police officer not below the rank of assistant sub-inspector (section 107(1)

Motor Vehicle Act

- **Section 95** empowers state governments to make rules for conduct of passengers in private vehicles.
- **Section 95**(2)(h) specifically empowers the State Governments to make Rules, that requires a passenger not to smoke in any vehicle on which a notice prohibiting smoking is exhibited.
- Under part III entry 48 prohibits the employment of a child (a person who has not completed his fourteenth year of age) in any workshop where Bidi making and tobacco processing including manufacturing of tobacco, tobacco paste and handling of tobacco in any form is carried out.
- Amendment to the Child Labour (Prohibition and Regulation) Act, 1986 has been passed that totally bans child labour in any industry.
- **Section 2** (28) "misleading advertisement" in relation to any product or service, means an advertisement, which—

  (i) falsely describes such product or service; or

  (ii) gives a false guarantee to, or is likely to mislead the consumers as to the nature, substance, quantity or quality of such product or service; or

  (iii) conveys an express or implied representation which, if made by the manufacturer or seller or service provider thereof, would constitute an unfair trade practice; or

  (iv) deliberately conceals important information;

- **Section 2** (47) "unfair trade practice" means a trade practice which, for the purpose of promoting the sale, use or supply of any goods or for the provision of any service, adopts any unfair method or unfair or deceptive practice including any of the following practices, namely:—

  (i) making any statement, whether orally or in writing or by visible representation including by means of electronic record, which—

  (a) falsely represents that the goods are of a particular standard, quality, quantity, grade, composition, style or model;

- Municipal laws being used for licensing eateries / restaurants likewise for shops selling tobacco products.
- Compliance with COTPA precondition to providing license or its renewal(Municipal Corporation of Greater Mumbai)
- The Municipal Corporation of Chandigarh City also requires license for selling tobacco products in the city.
- The Himachal Prohibition of Sale of Loose Cigarettes and Beedis and Regulation of Retail Business of Cigarettes and Other Tobacco Products Act, 2016. The Act makes compulsory registration for carrying retail business of any tobacco products.
- Municipal Acts of Bihar, Jharkhand, Uttar Pradesh, West Bengal, Kerala etc., used for compulsory licensing of tobacco trade.

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