COMPARISON OF ACUTE PHYSIOLOGY AND CHRONIC HEALTH EVALUATION (APACHE II) PHYSIOLOGICAL AND OPERATIVE SEVERITY SCORE FOR ENUMERATION OF MORTALITY AND MORBIDITY (POSSUM) AND ESTIMATION OF PHYSIOLOGIC ABILITY AND SURGICAL STRESS (EPASS) SCORING SYSTEMS IN PREOPERATIVE EVALUATION OF PATIENTS PLANNED FOR ORAL CANCER SURGERY

By

DR. S.AKSHAYA

DISSERTATION SUBMITTED TO

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND

RESEARCH CENTRE, KOLAR

In partial fulfillment of the requirements for the degree of

MASTER OF SURGERY

IN

OTORHINOLARYNGOLOGY

Under the guidance of

DR. S.M. AZEEM MOHIYUDDIN, MBBS, MS (ENT), FICS., FACS., MNAMS, SEKHSARIA FELLOWSHIP IN HEAD AND NECK SURGERY

DEPARTMENT OF OTORHINOLARYNGOLOGY
SRI DEVARAJ URS MEDICAL COLLEGE
TAMAKA KOLAR
2023

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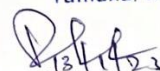
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ABSTRACT

BACKGROUND:

Oral cavity malignancies are most common non communicable diseases in many parts of globe. India accounts for fifth position in existence of oral cavity cancer which is because of high incidence of chewing tobacco and betel quid. Occurrence of oral cavity malignancies in Kolar district in Karnataka is high. Majority of the patients in Kolar present as locally advanced cancers - stage T3 and T4, requiring major and sometimes mutilating surgeries and reconstruction. In literature, few studies have evaluated the patients pre-operatively by various scoring systems like APACHE II, ASA, POSSUM, EPASS etc, which has been used prior to major surgical procedures. These scoring systems could aid in predicting outcome of surgery with regards to wound healing, post-op complications, and length of ICU and hospital stay and thereby inferring which scoring systems is more reliable and feasible for patients.

OBJECTIVES:

1. To assess patients undergoing oral cancer surgery using APACHE 2, EPASS and POSSUM scoring systems preoperatively.

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METHODS:

77 biopsy proven oral cancer patients planned for major surgery at R.L.J.H and Research Centre Tamaka, Kolar from January 2021 to July 2022 after fulfilling the inclusion criteria and signing an informed consent included in the study. Patients scored using each of these scoring systems (APACHE II, EPASS and POSSUM) preoperatively and the surgical outcome with regards to wound healing, post-op morbidities, and time span of ICU and in-patient duration were documented. Scoring systems compared among each other to find the most suitable scoring system for our population.

RESULTS:

This prospective observational study done in Kolar, had 70% of patients as female, with majority of patients in the age group more than 60 years. The one site involved was Buccal mucosa and lower GBS due to the usage of quid in those areas overnight. The most common post-operative complication was oro-cutaneous fistula which was managed conservatively. However there was no statistical significance found between the post-operative complications and the three scores. With regards to ICU stay, APACHE II was not statistically significant whereas EPASS and POSSUM were statistically significant. The APACHE II score exhibited a stronger predictive ability than EPASS and POSSUM according to the ROC curve study for predicting post-operative outcome.

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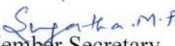
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PRIOR PERMISSION TO START OF STUDY

The Institutional Ethics Committee of Sri Devaraj Urs Medical College, Tamaka, Kolar has examined and unanimously approved the synopsis entitled **"Comparison of acute physiology and chronic health evaluation (APACHE2) physiological and operative severity score for enumeration of mortality and morbidity (possum) and estimation of physiologic ability and surgical stress (EPASS) scoring systems in preo"** being investigated by **DR. S AKSHAYA,** Dr. S M Azeem Mohiyuddin in the Department of ENT at Sri Devaraj Urs Medical College, Tamaka, Kolar. **Permission is granted by the Ethics Committee to start the study.**

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Last but not the least, I wholeheartedly thank all my patients and their families who submitted themselves most gracefully for this study. To these stoic people who showed great strength despite their suffering, let me say, I am greatly indebted…Thank you and God bless.

DR. S. AKSHAYA

LIST OF ABBREVIATIONS

APACHE II	Acute Physiology And Chronic Health Evaluation
EPASS	Estimation Of Physiologic Ability And Surgical Stress
POSSUM	Physiological And Operative Severity Score For Enumeration Of Mortality and Morbidity
RLJH	R.L. Jalappa Hospital
GBS	Gingivo-Buccal Sulcus
ROC	Receiver Operating Characteristic Curves
SCC	Squamous Cell Carcinoma
HPV	Human Pappiloma Virus
PMMC	Pectoralis Major Myocutaneous Flap
SCM	Sternocleidomastoid
CRS	Comprehensive Score
PRS	Physiologic Ability
SSS	Surgical Stress
ASA	American Society Of Anesthesiology
CT	Chemotherapy
RT	Radiotherapy
AUC	Area Under Curve
RMT	Retromolar Trigone
ICU	Intensive care unit
GCS	Glasgow Coma scale
PPV	Positive predictive value
NPV	Negative predictive value

ABSTRACT

BACKGROUND:

Oral cavity malignancies are most common non communicable diseases in many parts of globe. India accounts for fifth position in existence of oral cavity cancer which is because of high incidence of chewing tobacco and betel quid. Occurrence of oral cavity malignancies in Kolar district in Karnataka is high. Majority of the patients in Kolar present as locally advanced cancers - stage T_3 and T_4, requiring major and sometimes mutilating surgeries and reconstruction. In literature, few studies have evaluated the patients pre-operatively by various scoring systems like APACHE II, ASA, POSSUM , EPASS etc, which has been used prior to major surgical procedures. These scoring systems aids in predicting outcome of surgery with regards to wound healing, post-op complications, and length of ICU and hospital stay and thereby inferring which scoring systems is more reliable and feasible for patients.

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RESULTS:

This prospective observational study done in Kolar, had 70% of patients as female, with majority of patients in the age group more than 60 years. The most common site involved was Buccal mucosa and lower GBS due to the chewing of quid in those areas overnight. The most common post-operative complication was oro-cutaneous fistula which was managed conservatively. However there was no statistical significance found between the post-operative complications and the three scores. With regards to ICU stay, APACHE II was not statistically significant whereas EPASS and POSSUM were statistically significant. The APACHE II score exhibited a stronger predictive ability than EPASS and POSSUM according to the ROC curve study for predicting post-operative outcome.

CONCLUSION:

All three scoring systems were able to predict the post-operative outcome for patients. ROC curve was better in APACHE II than the other two scoring systems in predicting surgical outcome. Hence APACHE II is slightly better compared to other two scoring systems in predicting post-operative outcome.

KEY WORDS: APACHE II, EPASS, POSSUM, post-operative complications.

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INTRODUCTION

INTRODUCTION

One of the most prevalent non-communicable diseases in the world is cancer.[1] In our country head and neck malignancies accounts for 30% of all malignancies, among them most common are oral cancers.[2] South and Southeast Asia has high incidence in oral cavity cancer. More than 90% of oral cavity malignancies are SCC.[1] India accounts for fifth position in existence of oral cavity cancer which is due to high incidence of tobacco and betel quid chewing.[3] Addiction to various forms of non smoking tobacco intake (snuffing or chewing tobacco), alcohol and areca nut consumption, smoking and Human Papilloma Virus (HPV) etc are predisposing causes for oral cancer.[4]

Majority of individuals have locally advanced disease at presentation requiring aggressive multimodality treatment which can lead to morbidity, loss of functionality and deformities hence requiring major reconstructions.

Mastication, deglutition, maintaining oral competency, and articulation for speech are the oral cavity's crucial tasks.[5] To achieve good quality of life and longevity, many elements must be taken into consideration before choosing modality of treatment, and each patient's demands should be looked upon when designing treatment. Surgery is still a powerful treatment for oral cancers, and the primary treatment option depends on the disease's stage.[6]

The purpose of surgery is to remove adequate tumor tissue to leave a sufficient tumor-free margin. Inadequate removal of cancer cells lowers survival rates and raises the chance of local and regional recurrences. Large tumor free margin excision, however, may lead to more aesthetic and functional morbidities. Hence 1-cm tumor free margin is acceptable.[7,8]

The occurrence of the oral malignancies in Kolar district in Karnataka is high. Majority of the patients in Kolar present as locally advanced cancers - stage T_3 and T_4, requiring major and sometimes mutilating surgeries and reconstruction which mandates long operating time and anesthesia. In addition these patients have other disabilities due to malignancy like trismus, speech and voice impact, dysphagia due to structural and functional defect and impaired quality of life. This leads to poor oral hygiene and poor nourishment of the patient which increases the risk of postoperative complications with prolonged ICU or hospital stay and

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makes them unfit for post-surgery adjuvant treatment without which possibility of recurrence of cancer is high.[9]

In literature, few studies have evaluated the patients pre-operatively by various scoring systems like APACHE II, ASA, POSSUM etc. which has been used prior to major surgical procedures. These scoring systems could help in predicting the outcome with regards to wound healing, metabolic derangements, length of ICU stay and hospital stay after major surgeries. EPASS is also one similar scoring system developed by Japanese for oral cancer surgery.[10,11]

AIMS AND OBJECTIVES

AIM OF STUDY

In our study we intend to score patients planned for major oral cancer surgery by each of these systems(APACHE 2 , EPASS and POSSUM) and document the surgical outcome with regards to wound healing, post-operative complications, and length of ICU and hospital stay and thereby document which of these scoring systems is more reliable and feasible for our patients.

OBJECTIVES OF STUDY

1. To assess patients undergoing oral cancer surgery using APACHE 2, EPASS and POSSUM scoring systems preoperatively.

2. To compare the accuracy of the above mentioned scoring systems in predicting the outcome of surgery with regard to wound healing, post-operative complications and duration of ICU and hospital stay.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

HISTORY OF CANCER

Looking back to the oldest description of cancer, it was documented to be around 1500-3000 BC. In Greek, carcinoma means 'a crab', and in Latin it is called "Cancer". Cancer is a term used to characterize abnormal growth of cells, which invade into normal tissue and spread to various organs in various directions.[7]Since antiquity in India cancer like illness has been noted . The actual diagnosis of cancer began in the 19th century, and the burden of cancer started to raise in the 20th century.[12]

Rudolf Virchow, who is the "founder of cellular pathology" explained the pathologic basis for the study of cancer, which gave us a better knowledge of the disease process. This in turn, formed the basis for the development of cancer surgeries. The excised specimen must be examined from which a precise diagnosis is made. More importantly, the pathologists must report about the completeness of tumour resection.

John Hunter (1728-1793) was the one who suggested that if a tumour had not involved surrounding tissues and was "mobile", then it could be managed by surgery.[13] Thus, he laid the foundation for surgical oncology speciality.

Later Billroth, Hadley and Halsted, were the three surgeons, who contributed substantially to surgery of these cancer. Their work formulated a protocol that emphasized removal of the entire tumour along with regional lymph nodes. Oral cavity cancer surgery was primarily based on Halsted's principles which was "the tumour and its lymphatic drainage should be removed". It later expanded to removal of all the tissue en-bloc along with intervening tissue.

Sir Henry T. Batlin, surgeon from St. Bartholomew's Hospital, London, in 1885 A.D, performed wide excision of head and neck malignancies with mandibular excision and excision of lymphatics of upper neck. He and Kocher emphasized the advantage of excising metastatic cervical lymph nodes.

However, en bloc radical dissection of neck nodes was first explained by George Crile in 1906 A.D. His classic report provided the basis for the technique of radical neck dissection, which is practiced commonly even today.

The first "commando" operation, was performed by Grant Ward in 1932 A.D. Since 1942 this en bloc excision of primary within the oral cavity including portion of the mandible combined with the radical neck dissection was being performed regularly.

H.Martin coined the term composite resection (previously known as COMMANDO operation). It is a surgical procedure in which the primary tumour in oral cavity or oropharynx is removed in continuity with a segment of mandible along with a neck dissection.

Stephan Ariyan in 1979 A.D, described the PMMC flap, which is also called as the "work horse" of head and neck reconstruction particularly in developing countries. It is dependent on the thoracoacromial artery's pectoral branch.

In the period of antibacterial chemotherapy, better wound management, better diagnostic tools, advances in pathological techniques, improved surgical techniques and micro vascular free tissue transfer for effective reconstruction, development in anaesthesia and transfusion techniques, all these improved the prognosis of cancer surgery significantly.[14]

ORAL CAVITY - ANATOMY

The various anatomical subsites in oral cavity, described by the AJCC staging[15] are :

- Lip

Gingiva - Upper alveolus

       - Lower alveolus

-Floor of mouth

-Tongue (Anterior 2/3rd)

-buccal mucosa

-RMT

 -Hard palate

Fig 1: - Oral cavity - subsites
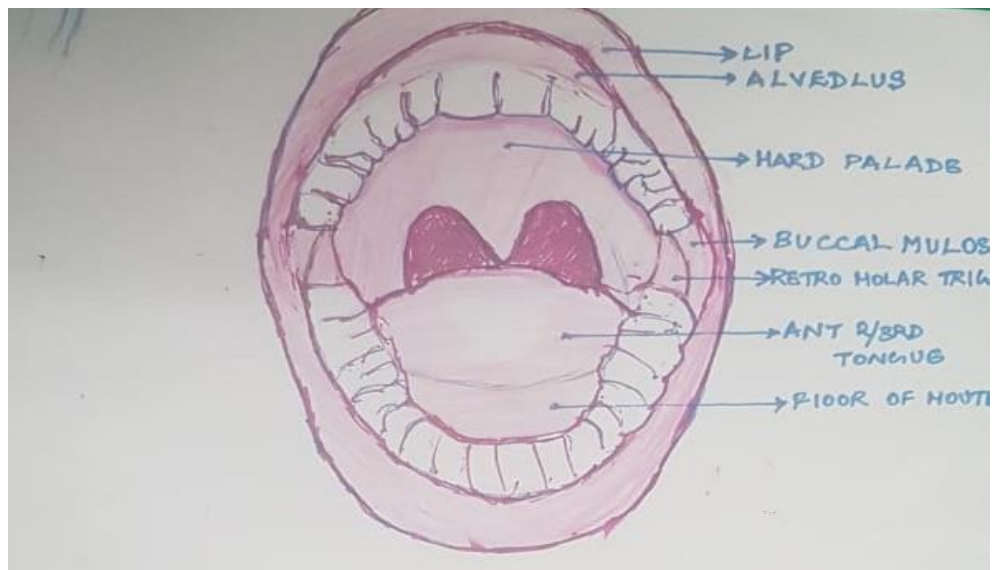
(i)Lip: The vermilion skin border is where the lip starts. The area of the lip that touches the opposing lip is known as the vermilion surface. Lip is divided into upper lip and lower lip, which come together at oral commissure (also known as angle of mouth).

(ii)**Buccal mucosa:** It is the mucous membrane that lines the inner aspect of cheek and lips from the point where cheek meets the lips till the point where the mucosa attaches to the upper alveolar and lower alveolar ridges and to the pterygomandibular raphe.

(iii)Lower alveolar ridge: The mucosal lining of the mandibular alveolar process reaches the mucosa of the floor of mouth from where it inserts into the buccal sulcus, posteriorly extending to the mandibular ramus.

(iv)Upper alveolar ridge: The hard palate is connected to the upper gingivo-buccal sulcus via the mucosal lining of maxillary alveolar process. The posterior boundary reaches the pterygopalatine arch's superior end.

(v)Retromolar trigone: This is a triangular region of the mandible's ascending ramus that is lined with mucosa. The lower third molar tooth forms the anterior boundary, while the maxillary tuberosity serves as the apex.

(vi)Floor of the mouth: This semilunar area starts from the inner side of the mandibular

alveolar ridge till the ventral surface of the tongue, above the base of the mylohyoid and hyoglossus muscles of tongue. The posterior boundary is the lower portion of the tonsil's anterior pillar. The tongue is split into two sides by the frenulum, which also houses the openings for the submandibular and sublingual salivary gland ducts.

(vii)Hard palate: The palatine process of the maxilla forms the space between the two upper alveoli, and mucous membrane lines it. It reaches the posterior margin of the palatine bone from the superior alveolar ridge's inner surface.

(viii)Anterior 2/3rd of the tongue: From the tongue tip anteriorly to the line of circumvallate papillae posteriorly, it is the portion of the tongue that is freely moveable. It reaches the intersection of the tongue's underside and the mouth's floor inferiorly. It is made up of four surfaces: the dorsum, ventral surface, tip, and lateral surface.

BLOOD SUPPLY OF ORAL CAVITY

The external carotid artery's branches provides blood to oral cavity. Tongue derives blood supply from Lingual artery. Lips, buccal mucosa and alveolar ridges derive their blood supply from facial arteries, internal maxillary and inferior alveolar arteries. Greater palatine arteries supplies palate and upper alveolus.[16,17]
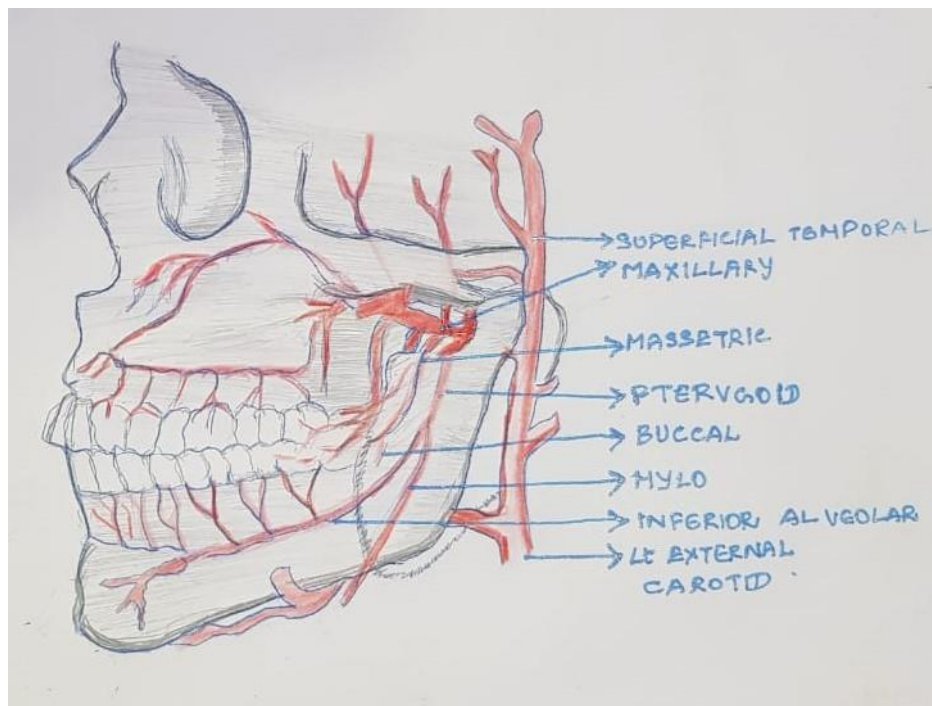
Fig 2: Oral cavity – Blood supply

ORAL CAVITY – NERVE SUPPLY
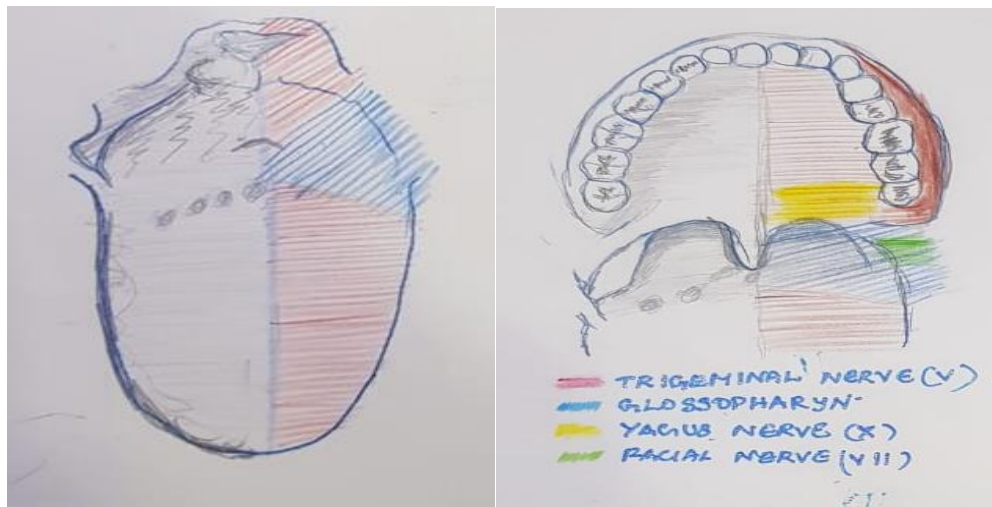
Fig 3: Nerve supply of Oral cavity

Sensory component of nerve supply to oral cavity is supplied by sensory component of second and third division of trigeminal nerve, through superior and inferior alveolar and lingual nerves. Chorda tympani provides special senses of taste and secretomotor fibres to the salivary glands as it traverses along the lingual nerve. Facial nerve takes the motor control of the lips and cheek. The motor nerve fibres of the hypoglossal nerve innervate muscles of tongue. Actions of medial and lateral pterygoid muscles and their movements are controlled by the motor components of the 2nd and 3rd divisions of trigeminal nerve.[16,18]

HISTORY OF LYMPHATIC SYSTEM

The initial description of lymphatic system was given by Gaspero Aselli, professor of anatomy and surgery from Italy, in 1662. The anatomy and physiology of the lymphatics was precisely described by William Hunter, William Cruikshank, and William Hewson in London in 1786, in their monograph by Cruikshank.[19]

Sappey went on to discuss the anatomy of the entire lymphatic system, and his illustrations of lymphatic flow are still useful. At this period, Virchow and other researchers hypothesised that lymph nodes served as a barrier to the development of cancer and that the disease developed in stages, starting with a primary tumour and moving on to local lymph nodes before spreading to systemic areas. This notion led to the development of radical surgical techniques, such as Crile's radical neck dissection.[19,20]

LYMPH NODE GROUPS

Cervical lymph nodes are classified into various oncological levels and have specific area of drainage.

Level I: Consists of a)submental (Ia) b)submandibular (Ib) lymph nodes

Submental nodes are present in between anterior bellies of digastric

The anterior and posterior bellies of digastric, the inferior border of hyoid bone and superior border of mandibular body defines the boundaries of the submandibular lymph node.

Level II: Extends from base of skull superiorly to hyoid bone inferiorely and it comprises of upper jugular nodes. In anterior triangle of neck (a vertical line dropped from angle of mandible to posterior border of sternocleidomastoid). It is further classified into 2a(anterior) and 2b(posterior) by spinal accessory nerve.

Level III: Hyoid bone borders the area superiorly till the lower cricoid border inferiorly, midline to posterior sternocleidomastoid border, this area comprises of middle jugular nodes.

Level IV: Extends superiorly from the level of the cricoid cartilage up to the clavicle below, in anterior triangle of neck (IVa and IVb). Contains the lower jugular nodes.

Level V: Bounded by clavicle inferiorly, the SCM (posterior border) anteriorly and trapezius muscle (anterior border) posteriorly. It contains the posterior triangle's lymph nodes and is split into Va and Vb by the omohyoid's inferior belly.

Level VI: Extends from the suprasternal notch in the lower part to the hyoid bone in the upper part. The lateral barrier is formed on each side by the carotid sheath's medial border. Contains the middle compartment's lymph nodes."

Level VII: Contains lymph nodes in superior mediastinum, inferior to suprasternal notch.[16,21,22]"
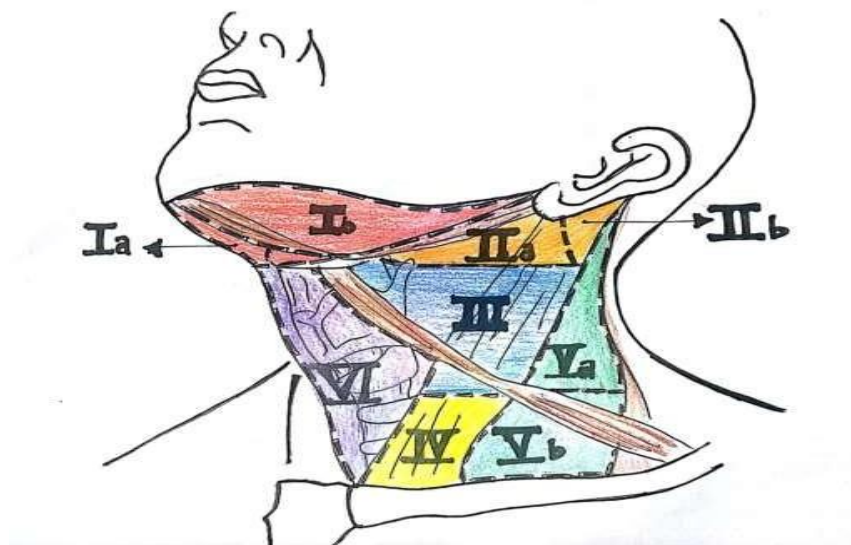
Fig 4: Levels of Lymph nodes in Neck

ORAL CAVITY CANCER

EPIDEMIOLOGY:

In history man has always been trying to conquer malignant diseases. However, it still remains a major cause of morbidity and death. About nine million cancers are being reported new every year in world.

Bangladesh, India, Sri Lanka & France have high rates with India accounting for around 30% of newly detected cases.[23] About 7 lakhs new cases are detected in India, and about 3.5 lakhs people die of cancer every year.[24]

According to the cancer registry in Kidwai Institute of Oncology, Karnataka, on an average of about 5000 new cancers are registered per year.[25] Oral cavity cancer ranks among top 3 cancers in India. In India Age adjusted rates of oral cancers is 20 per 100,000 people and accounts for over 30% of all cancers.[26]

In western world there is a higher prevalence of cancer in primary subsite such as tongue and floor of mouth . Whereas in India, the most frequently encountered primary sites are the buccal mucosa and lower alveolus.[21,27]

Malignancy of buccal mucosa accounts for 40% of oral cancers in South East Asia. 85% cases occur in more than 50 years age group, except in developing countries where onset can be earlier due to tobacco and pan chewing habits. Floor of mouth cancer accounted for 18-33% of oral cavity cancers, seen more among men in their 6th-7th decade. 22-39% of oral malignancies arise in the lateral aspect of tongue, most commonly in middle 1/3rd.[16]

Incidence of Retromolar trigone cancer is 6 - 7% and is more common in males. Carcinoma incidence in upper alveolus is 3.5 – 6.5% & hard palate is 1 – 3%. Oral cancers are more common in males whereas hard palate carcinomas is common in females due to reverse smoking in certain area. Lower alveolar cancers account for 7.5 – 17.5 % of oral cancers.[15]

However, in Kolar region most common malignancy is carcinoma of buccal mucosa.[9] It is more prevalent in women due to addiction to tobacco and quid chewing. In India, patients present in advanced stage and both buccal mucosa and lower alveolus will be involved making it difficult to identify the epi-centre or starting point of tumour.

Such tumours involving the buccal mucosa and lower alveolar complex have been nick named **"Indian oral cancer"** and are high volume disease.[26]

ETIOLOGY:

The cause of oral cancer is yet to be completely understood. Several risk factors have been implicated. Due to the high rates of smoking, chewing betel nut, and alcohol use in Southeast Asia, oral cancer is a significant problem.[28]

1] Smoking:

Tobacco is smoked more often in the form of cigarette and bidi. Some smoke a chutta (a cigar), with the burning end inside the mouth. Chemical carcinogens in the burning tobacco or repeated thermal injury are agents, which are risk factors for oral cancer. Risk increases with the amount smoked and with the total cumulative lifetime smoking years. Tobacco is smoked commonly in the form of bidi, a type of cheap cigarette made by rolling a rectangular dried piece of tendu leaf (Diospyros melanoxylon). The length varies from 4 cms to 7.5 cms. As compared with cigarette, bidi has high content of several toxic products such as carbon monoxide, ammonia, hydrogen cyanide, phenol and carcinogenic hydrocarbons.

The other ways of smoking tobacco are clove-flavoured cigarette, various forms of pipes (wooden, clay, metal), the hookah (the Hubble bubble or water pipe), cheroots (or chuttas) and dhumtis. Tobacco may be used in raw or as processed mixtures and as a pyrolised form. The raw forms are used with lime and with areca nut (Mawa-smokeless tobacco).

Khaini is a combination of freshly powdered tobacco and slaked lime. It is kept for hours in the lower gingivolabial sulcus and chewed, which is risk factor for khaini cancer (squamous cell carcinoma of the lower lip). Processed forms, for example zarda, gutkha, and Manipuri tobacco are industrial products. The pyrolised (roasted) forms of tobacco (mishri, bajjar, etc) are used as dentifrice. Oral use of snuff is also practised in specific areas. Brings about hyperacetylation and hypomethylation of histones which silences tumour suppressor genes.[29]

2] Spirits: - Consumption of calvados {a pot distilled spirit}

3] Sepsis: - Septic and decayed teeth.

4] Sharp teeth: - improper oral care and ill-fitting dentures.[30]

5] Spices

6] Infections – For cell proliferation to occur, inflammation-producing cytokines are stimulated by syphilis, Porphyromonas gingivalis, and Fusobacterium nucleatum. Apoptosis, cellular invasion, and migration through the host cell are inhibited, which results in genomic changes.[32]

7] Betel and tobacco quid chewing habit: - The quid is made of an areca nut kept inside betel leaf, which is high in tannin, quick lime and tobacco. Oral cancer develops at the site where quid is habitually kept. Smoking along with chewing of betel quid enhances risk of oral malignancy by 20 to 30 times. *This is most common risk factor for oral cancer in our region(Kolar).*

Fig 5: Betel leaves coated with slaked lime and areca nut

8] Snuff dipping and other tobacco products

Fig 6: various forms of tobacco consumed

9] Alcohol: Alcohol consumption has a synergistic local effect of dissolving the carcinogen in the sump area of the mouth and a systemic downward effect on the immune system. Alcoholics often have nutritional problems. Brings about hypermethylation of histone.[16]

10] Industrial chemicals

11] Viruses: Herpes simplex virus and the Human papilloma virus (subtype 16).[33]

12] Immune status: - Immune deficiency due to low cell mediated immunity.

13] Genetic factors: - The majority of spontaneous tumours arise via a multi-step process of accumulating genetic changes. The loss of chromosomal heterozygosity caused by these changes has an impact on the behaviour of epithelial cells. This then triggers a chain of events that eventually reach the stage of invasive squamous cell carcinoma. Clinical and microscopic pathology, from hyperplasia to tumour invasiveness, reflect the corresponding genetic alterations. Over expression of mutated p53, p16, p21 and other tumour suppressor genes may predispose to development of cancer and recurrence following treatment.

Overexpression of c-erbB-2 has shown correlation with nodal disease and metastasis and worsened survival.

Oral cavity cancers have been linked to the diseases that are characterised by mutagen sensitivity, such as Xeroderma pigmentosum, Fanconi's anaemia, and Ataxia telangiectasia. The cytochrome p450 enzyme system's inducibility may be another pertinent genetic marker.[31,34]

14] Social status: - Related to social habits and to low socio-economic status

15] Diet

16] Occupation: Employment in textile industries

TREATMENT OF ORAL CANCER:

Surgery is a proven treatment for the most oral cancer cases. Most frequently given as a post-operative treatment, radiation is used as an adjuvant with surgery in the majority of patients with advanced cancer. In the 1950s, 1960s, and 1970s, chemotherapy was viewed as palliative in the treatment of oral carcinoma. Clinical trials using induction chemotherapy, however, showed that a considerable number of patients responded to chemotherapy once Cis-platinum was introduced.

Treatment includes resection of primary tumour, traditionally a 10–15 mm resection margin is advised excluding lip, along with resection of primary tumour neck dissection is done to clear neck nodes and following which reconstruction of primary defect area is done.[35] Post-operatively based on histopathology report patient receives adjuvant treatment either RT or CT+RT (if patients have close tumor margins, positive lymph nodes and depth of invasion > 10mm in histopathological evaluation.) The features of primary tumour (tumour factors), patient (patient's factors), and treatment delivery force (team factors) are the factors that affect the decision of initial treatment (physician factors).

PHYSICIAN FACTORS: -

Surgery

Radiotherapy

Chemotherapy

Combined modality treatment

Dental Rehabilitation services

Prosthetics

Support services

Photodynamic therapy

Immunotherapy

Gene therapy

Most therapies other than surgery are not known to be effective against large tumours. Therefore, the most promising results may be obtained with treatment of non- metastatic tumours by surgical removal of the primary tumour followed by adjuvant radiotherapy or radiotherapy and chemotherapy.

TUMOUR FACTORS:

Site of lesion

Size of lesion (T stage)

Location - anterior versus posterior

Proximity to bone (mandible)

Nodal metastasis

Previous history of any treatment

Histology -type, grade, depth of invasion

PATIENT FACTORS:

Age/Gender

General health condition

Tolerance

Occupation

Acceptance and compliance with regards to treatment

Life style (smoking, drinking, tobacco chewing)

Socio-economic consideration.[36]

RECONSTRUCTION[37,38]

Oromandibular reconstruction continues to be one among the challenging areas of head and neck reconstruction. Reconstruction of resulting defect can be done by the following methods:

Split thickness skin grafts/ Full thickness skin grafts

1. Buccal, Palatal, Periosteal Mucous membrane flaps
2. Tongue flaps
3. Posteriorly based lateral tongue flap
4. Posteriorly based bilateral tongue flap
5. Anteriorly based ventral tongue flap
6. Masseter flap
7. Nasolabial flap
8. Medial based deltopectoral flaps
9. Forehead flap
10. Sternocleidomastoid myo-cutaneous flap
11. Trapezius
12. Platysma myo-cutaneous flap

13. Pectoralis major myo-cutaneous flap

14. Latissimus dorsi myo-cutaneous flap

15. Costochondral grafts

16. Osteo-myocutaneous flap- fifth rib with pectoralis major myo-cutaneous flap

17. Spine of scapula with trapezius

18. Free osteo-cutaneous groin flap

19. Free osteo-cutaneous fibula flap

20. Scapular Osseo-cutaneous flap

21. Radial forearm flap

22. Radial forearm free osteo-cutaneous flap

23. Free fibula and osseo-integrated implants

Larger the tumor volume the defect will be greater and more difficult for a surgeon to reconstruct. When quick single stage reconstruction can be accomplished with adequate success rates and little morbidity, it is always preferred to delayed reconstruction. The development of muscular contracture is stopped and the mandibular shape is restored when the mandible is immediately restored. Reconstruction that is put off interferes with radiation and subsequent healing.

The bone to mucosa relationship of the periosteum of the alveolar ridge and gingival mucosa is most difficult to duplicate and is necessary for wearing dentures. Preservation of chewing, provision of a base for dental appliances and preservation of a normal appearing lower third of the face are achieved by preservation of the buccal sulcus and the oral floor, which are all essential for maintenance or restoration of the mandibular contour

SCORING SYSTEMS:

In an effort to avoid unfavourable outcomes following surgery, a number of scoring systems have been invented to predict postoperative result, including morbidity and death. In this study we are using three scoring systems to evaluate patients pre operatively.

1. APACHE II

2. EPASS

3. POSSUM

APACHE II[10,39,40]

Table 1. The APACHE II Severity of Disease Classification System*

	Score				
Physiological Variable	0	1	2	3	4
Temperature, °C	NA	34.0-35.9	32.0-33.9	30.0-31.9	≤29.9
	36.0-38.4	38.5-38.9	NA	39.0-40.9	≥41.0
Mean arterial blood pressure, mm Hg	70-109	NA	50-69	130-159	≤49
	NA	NA	110-129	NA	≥160
Heart rate, ventricular response, beats/min	70-109	NA	55-69	40-54	≤39
	NA	NA	110-139	140-179	≥180
Respiratory rate, nonventilated or ventilated, breaths/min	12-24	10-11	6-9	35-49	≤5
	NA	NA	NA	NA	≥50
Oxygenation (A-aDO$_2$ or PaO$_2$), mm Hg					
FIO$_2$<0.5 (record only A-aDO$_2$)	<200	NA	200-349	350-499	≥500
FIO$_2$≥0.5 (record only PaO$_2$)	>70	61-70	NA	55-60	<55
Arterial pH	7.33-7.49	7.50-7.59	7.25-7.32	7.15-7.24	<7.15
	NA	NA	NA	7.60-7.69	≥7.70
Serum sodium, mEq/L	130-149	150-154	120-129	111-119	≤110
	NA	NA	155-159	160-179	≥180
Serum potassium, mEqL	3.5-5.4	3.0-3.4	2.5-2.9	6.0-6.9	<2.5
	NA	5.5-5.9	NA	NA	≥7.0
Serum creatinine, mg/dL (double point score for acute renal failure)	0.6-1.4	NA	<0.6	2.0-3.4	≥3.5
	NA	NA	1.5-1.9	NA	NA
Hematocrit, %	30.0-45.9	46.0-49.9	20.0-29.9	NA	<20
	NA	NA	50.0-59.9	NA	≥60
White blood cell count, ×10⁹/µL	3.0-14.9	15.0-19.9	1.0-2.9	NA	<1.0
	NA	NA	20.0-39.9	NA	≥40.0
Glasgow Coma Scale (GCS) score (score = 15–actual GCS)					

A. Total acute physiology score (sum of the 12 individual variable points)

B. Age Points

Age, y	Points
≤44	0
45-54	2
55-64	3
65-74	5
≥75	6

C. Chronic health points
If the patient has a history of severe organ system insufficiency or is immunocompromised, assign points as follows:
a. For nonoperative or emergency postoperative patients, 5 points
b. For elective postoperative patients, 2 points

Definitions
Organ insufficiency or immunocompromised state must have been evident before this hospital admission and conform to the following criteria:
- Liver: Biopsy-proven cirrhosis and documented portal hypertension; episodes of past upper gastrointestinal bleeding attributed to portal hypertension; or prior episodes of hepatic failure, encephalopathy, or coma.
- Cardiovascular: New York Heart Association class IV.
- Respiratory: Chronic restrictive, obstructive, or vascular disease resulting in severe exercise restriction, ie, unable to climb stairs or perform household duties; or documented chronic hypoxia, hypercapnia, secondary polycythemia, severe pulmonary hypertension (>40 mm Hg), or respirator dependency.
- Renal: Receiving chronic dialysis.
- Immunocompromised: The patient has received therapy that suppresses resistance to infection, eg, immunosuppression, chemotherapy, radiation, long-term or recent high-dose corticosteroids, or has a disease that is sufficiently advanced to suppress resistance to infection, eg, leukemia, lymphoma, or AIDS.

Abbreviations: A-aDO$_2$, alveolar-arterial oxygen tension gradient; APACHE, Acute Physiology and Chronic Health Evaluation; FIO$_2$, fraction of inspired oxygen; NA, not applicable.
SI conversion factor: To convert creatinine to micromoles per liter, multiply by 88.4.
*APACHE II score = A + B + C.

Fig 7: APACHE II score

- This scoring system was developed by William A Knaus.
- The main goal of developing the APACHE II score was to more explicitly employ mathematics to monitor the procedure and assess the results of care..
- It depicts general state of a patient in a perioperative context and assesses the patient's physiological status as well as surgical invasion. In many ICU's, a severity of disease categorization system called APACHE II is often used to stratify the prognosis of acutely unwell patients.

EPASS[10,41,42]

Table 1 Estimation of Physiologic Ability and Surgical Stress (E-PASS) and Acute Physiology and Chronic Health Evaluation (APACHE) II scoring systems

The E-PASS score consists of three parts for estimation of physiologic ability (PRS), surgical stress (SSS), and th comprehensive score(CRS). The formula for each score was as follows:

$PRS = -0.0686 + 0.00345X1 + 0.323X2 + 0.205X3 + 0.153X4 + 0.148X5 + 0.0666X6$

XI: age

X2: absence (0) or presence (1) of severe heart disease

X3: absence (0) or presence (I) of severe pulmonary disease

X4: absence (0) or presence (I) of diabetes mellitus

X5: performance status index (0–4)

X6: American Society of Anesthesiologists physiological status classification (1–5)

$SSS = -0.342 + 0.0139X1 + 0.0392X2 + 0.352X3$

XI: blood loss/body weight (g/kg)

X2: Operative time (hours)

X3: Extent of the skin incision (0: minor incision, 1: laparotomy or thoracotomy alone, 2: both laparotomy and thoracotomy)

$CRS = -0.328 + 0.396(PRS) + 0.976(SSS)$

Fig 8: EPASS score

- EPASS scoring system was invented by S.Yamashita et al

- When making surgical decisions and assessing the standard of care for patients who have major procedures, this score is helpful. This scoring system consists of three components CRS, PRS and SSS. Cumulative results of these three components gives the EPASS score.

- Predicting postoperative mortality and morbidity using E-PASS scoring system is a practical and straightforward method.

POSSUM[11,43,44]

Table 2. POSSUM Score

Variable	Score 1	Score 2	Score 4	Score 8
Age, y	≤60	61-70	≥71	NA
Cardiac signs	No failure	Diuretic, digoxin, antianginal, or hypertensive therapy	Peripheral edema; warfarin sodium therapy	Raised jugular venous pressure
Chest radiograph (heart)	NA	NA	Borderline cardiomegaly	Cardiomegaly
Respiratory history	No dyspnea	Dyspnea on exertion	Limiting dyspnea (1 flight)	Dyspnea at rest (rate, ≥30/min)
Chest radiograph (lung)	NA	Mild COPD	Moderate COPD	Fibrosis or consolidation
Mean systolic blood pressure, mm Hg	110-130	131-170 100-109	≥171 90-99	≤89
Pulse, beats/min	50-80	81-100 40-49	101-120	≥121 ≤39
Glasgow coma score	15	12-14	9-11	≤8
Hemoglobin, g/dL	13.0-16.0	11.5-12.9 16.1-17.0	10.0-11.4 17.1-18.0	≤9.9 ≥18.1
White blood cell count, ×10³/µL	4.0-10.0	10.1-20.0 3.1-3.9	≥20.1 ≤3.0	NA
Serum urea, mg/dL	≤21	22-28	29-41	≥42
Serum sodium, mEq/L	≥136	131-135	126-130	≤125
Serum potassium, mEq/L	3.5-5.0	3.2-3.4 5.1-5.3	2.9-3.1 5.4-5.9	≤2.8 ≥6.0
Electrocardiogram	Normal	NA	Atrial fibrillation (rate, 60-90)	Any other abnormal rhythm or ≥5 ectopics/min Q waves or ST/T-wave changes
Operative severity	Minor	Moderate	Major	Major plus
Multiple procedures	1	NA	2	>2
Total blood loss, mL	≤100	101-500	501-999	≥1000
Peritoneal soiling	None	Minor (serous fluid)	Local pus	Free-bowel content, pus, or blood
Presence of malignancy	None	Primary only	Nodal metastases	Distant metastases
Mode of surgery	Elective	NA	Emergency resuscitation within 2 h possible Operation <24 h after admission	Emergency (immediate surgery <2 h needed)

Abbreviations: COPD, chronic obstructive pulmonary disease; NA, not applicable; POSSUM, Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity.

SI conversion factor: To convert urea to millimoles per liter, multiply by 0.357.

Fig 9: POSSUM score

- Copeland et al. first introduced POSSUM as a method for normalising patient data in 1991, allowing for direct comparisons of patient outcomes despite differences in referral patterns and demographics.

- The POSSUM, which has 12 physiological and 6 operative variables, was created exclusively for surgical patients. It aids in predicting post-operative morbidity and mortality.

MATERIALS AND METHODS

MATERIALS AND METHODS

SOURCE OF DATA:

77 biopsy proven oral cancer patients planned for major surgery at R.L.J.H and Research Centre affiliated to SDUMC affiliated to SDUAHER, Tamaka, Kolar from January 2021 to July 2022 after fulfilling the inclusion criteria and signing an informed consent were included in the study. Prior permission was taken before the starting study from Institution Ethics Committee. Number: SDUMC/KLR/IEC/652/2020-21.

Sample size considering an alpha error of 5% at 80% Power, the estimated sample size for the prospective observational study will be 77 Oral Cancer patients. This sample size has been calculated from a study based on the scoring systems APACHE 2 and POSSUM by De Cássia Braga Ribeiro K, Kowalski LP conducted in 2003[10] for the present prospective cohort study it is calculated based on the correlation of APACHE2 with hospitalisation (R=0.22) and POSSUM with duration of hospitalisation (R=0.41),

FORMULA :

$$n = \frac{\left\{ z_{1-\frac{\alpha}{2}} \sqrt{2\,\pi_0(1-\pi_0)} + z_{1-\beta} \sqrt{\pi_1\,(1-\pi_1) + \pi_2\,(1-\pi_2)} \right\}^2}{(\pi_2 - \pi_1)^2}$$

Where

$$\pi_0 = \frac{\pi_1 + \pi_2}{2}$$

π_1 = Sensitivity of the new test

π_2 = Sensitivity of the reference test

α = Significance level

1- β = Power

STUDY DESIGN: PROSPECTIVE OBSERVATIONAL STUDY

STUDY PERIOD: January 2021 till July 2022

INCLUSION CRITERIA:

All patients of either gender aged between 40-70 years with biopsy proven oral squamous cell carcinoma staged T_3 and T_4 undergoing major surgery (resection of tumor, neck dissection and reconstruction)

EXCLUSION CRITERIA:

1. Patients with history of earlier radiotherapy
2. Second primary cancers
3. Patients found unfit for surgery on pre-anaesthetic evaluation.

FOLLOW UP PERIOD: 3 MONTHS

METHOD OF COLLECTION OF DATA
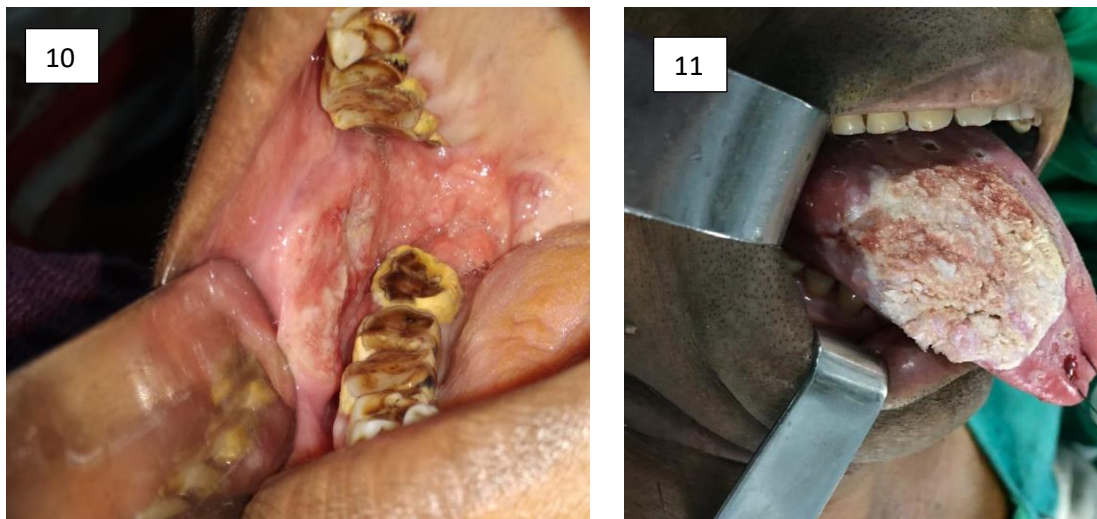
Fig 10: Lesion in Right Retromolar trigone staged T3 Fig 11: lesion in lateral border tongue

Patient with oral cancer staged T3 and T4 fulfilling both criteria (inclusion and exclusion criteria) were included in this study after obtaining informed written consent. They were treated according to current standard of care - composite resection/ resection of tumor with dissection of neck nodes and reconstruction of defect, followed by adjuvant radiotherapy or chemotherapy with radiotherapy if patients have close tumor margins, positive lymph nodes and depth of invasion > 10mm in histopathological evaluation. Prior to surgery patients were evaluated using the following three scoring systems:

A) APACHE 2 score (which comprises of Body temperature, Mean Blood Pressure, pulse rate, Respiratory rate, ph), Fraction of inspired oxygen (FiO2), Serum sodium, potassium, creatinine, Haematocrit, White blood cell count, GCS), Age, Nature of surgery – elective/emergency, h/o chronic condition), the final score were documented.

B) EPASS (which includes age, presence or absence of major health problems, ASA classifications, Performance Status Index, blood loss in ml/body weight, operating time, skin incision type (in this study we had taken incision as minor)), the final score were documented.

C) POSSUM score (which comprises of age, cardiac findings, chest radiography of heart and lungs, history of respiratory effort, mean Systolic Blood Pressure/pulse rate, GCS, blood investigations like White Blood Cell count, blood urea, haemoglobin, serum sodium, potassium, ECG, surgical severity, number of procedures, blood loss, mode of operation(elective/emergency), type of malignancy), the final   score were documented
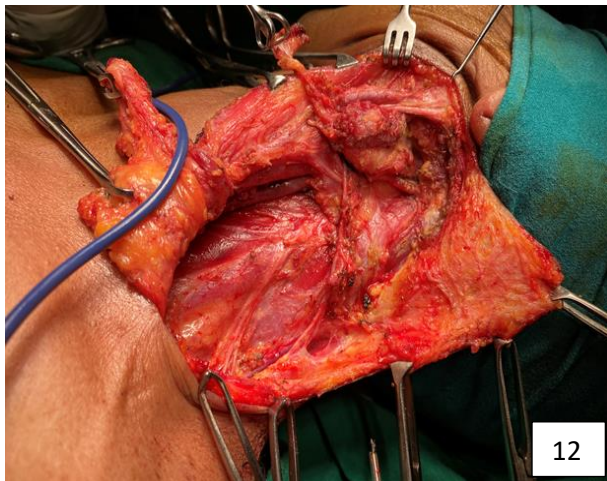
Fig 12: Neck dissection

Fig 13: Composite Resection + Modified Radical Neck Dissection

 The operation was done by same senior surgeon. Wound healing, postoperative complications if any, duration of ICU stay and duration of hospital stay were documented. The patients were followed up for three months after surgery and their performance scores were documented.

The accuracy of each scoring system in predicting the outcome of surgery with regards to wound healing, postoperative complications if any, length of ICU stay and length of hospital stay were compared.

STATISTICAL ANALYSIS:

Data entered in Microsoft excel and analyzed using SPSS 22 version software. Categorical data represented as Frequencies and proportions. **Chi-square test or Fischer's exact test** used to test significance for qualitative data.

Mean+/- standard deviation used in showing continuous variables. **Independent t test** used as statistical test to determine difference in mean among two quantitative variables. To determine mean difference between more than two quantitative variables, an ANOVA was utilised as test of significance.

Receiver operating characteristic curves (ROCs) was constructed for APACHE II, EPASS, POSSUM and Complication. Comparison of three score was done. Receiver operating characteristic (ROC) and optimal cut-off points were constructed for determination of (i)sensitivity, (ii)specificity, (iii)positive and negative predictive values. Test was interpreted based on a prediction of overall results and area under curve value 0.5. Greater than 0.8 under ROC curve indicated reasonable prediction.

Graphical representation of data: Data graphs were created using MS Excel and MS word

p value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

Statistical software: MS Excel**,** SPSS version 22 **(**IBM SPSS Statistics, Somers NY, USA) was used to analyze data.

OBSERVATIONS AND RESULTS

OBSERVATION AND RESULTS

Table 1: Distribution of subjects according to age group.

	Frequency	Percent
<40yrs	6	7.8
41-50yrs	19	24.7
51-60yrs	21	27.3
>60yrs	31	40.3
Total	77	100.0

Figure 14: Graph showing Distribution of subjects according to age group.
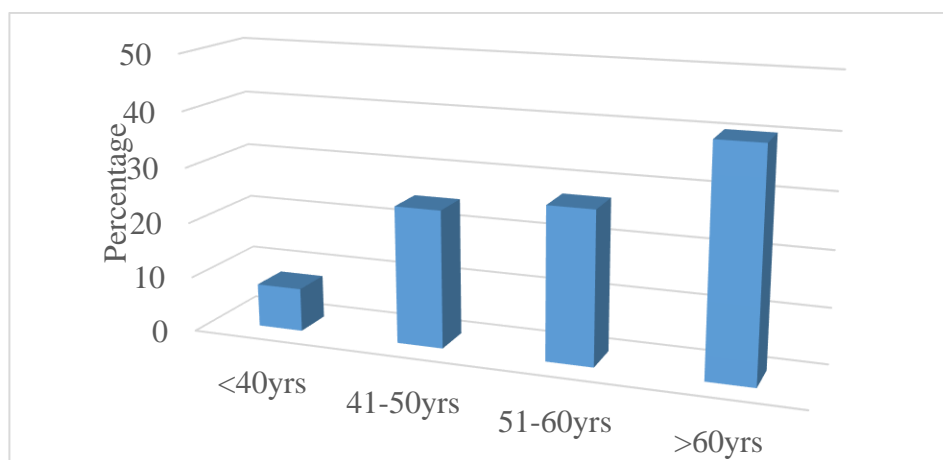
In our study majority of the patients were in the age group of more than 60 years (40.3%), 27.3 % were in the age group of 51 to 60 years, 24.7% were in the age group of 41 to 50 years, 7.8% were in the age group <40 years.

Table 2: Distribution of subjects according to sex

	Frequency	Percent
Female	54	70.1
Male	23	29.9
Total	77	100.0

Figure 15: Graph showing Distribution of subjects according to sex
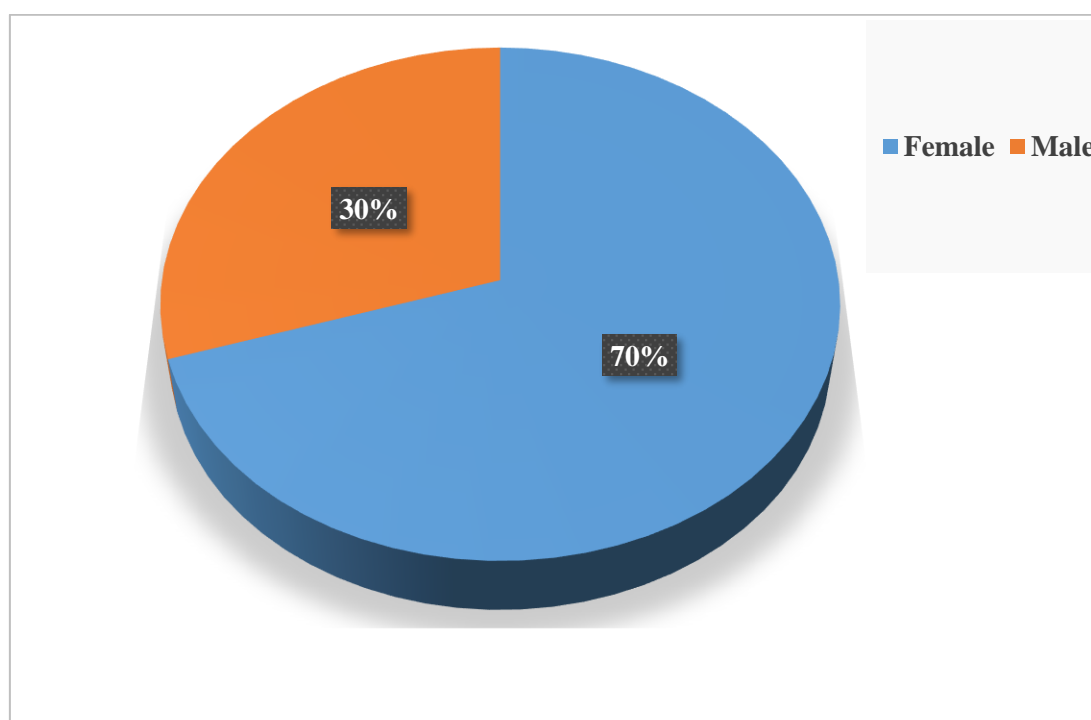
In our study, majority of the patients were females 70.1% and 29.9% were males.

Table 3: Distribution of subjects according to site.

	Frequency	Percent
Alveolus	7	9.1
Buccal mucosa	29	37.7
Floor of mouth	1	1.3
GBS	22	28.6
Hard palate	1	1.3
Mandible	1	1.3
Palate	1	1.3
RMT	4	5.2
Tongue	11	14.3
Total	77	100.0

Figure 16: Graph showing Distribution of subjects according to site.
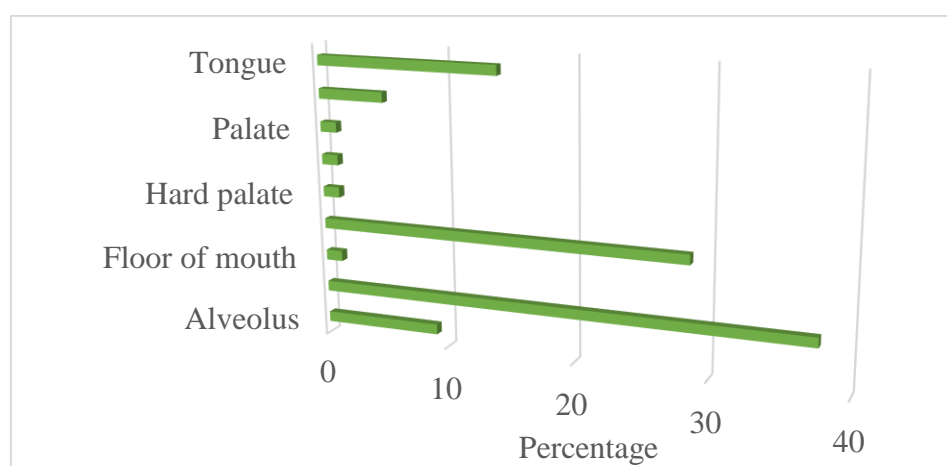
Out of the 77 patients in our study, the primary tumor in majority of the cases was in the subsite Buccal mucosa which was 29 patients (37.7%). The other sites involved were GBS with 22 patients (28.6%), Alveolus with 7 patients (9.1%), floor of mouth with 1 patient (1.3%), hard palate with 1 patient (1.3%), mandible with 1 patient (1.3%), soft palate with 1 patient (1.3%), RMT with 4 patients (5.2%), tongue with 11 patients (14.3%).

Table 4: Distribution of subjects according to tumor staging

	Frequency	Percent
T3	26	33.8
T4	51	66.2
Total	77	100.0

Figure 17: Graph showing Distribution of subjects according to tumor staging
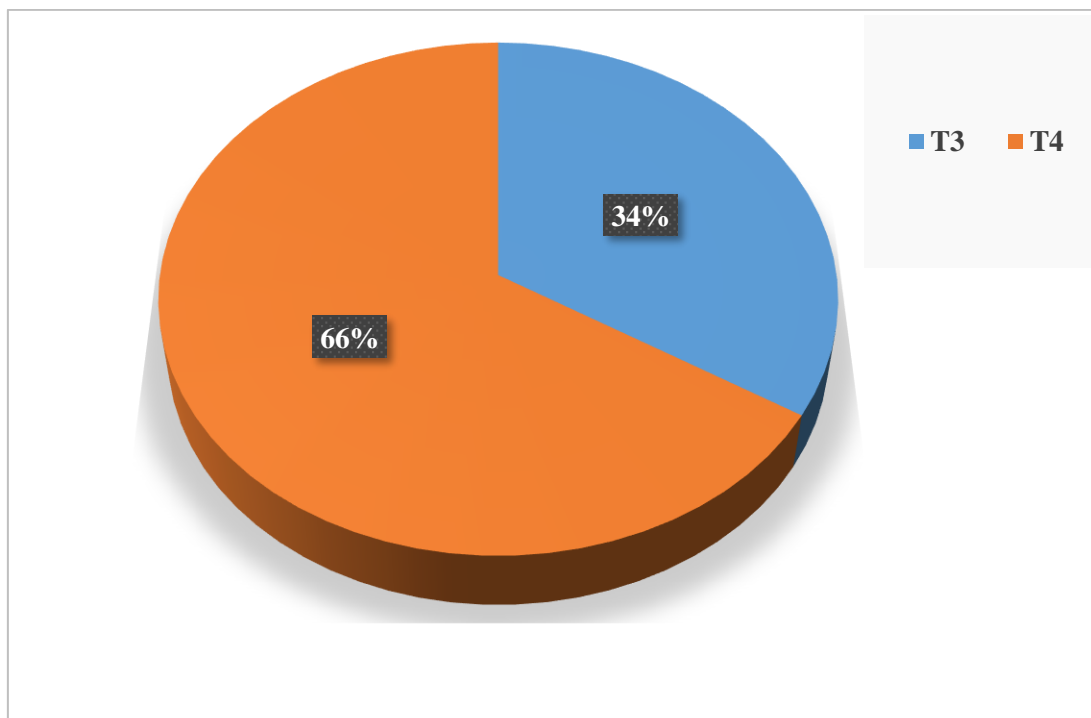
In our study patients with T3 stage were 26 (33.8%) and patients with T4 stage were 51 (66.2%).

Table 5: Distribution of subjects according to ICU stay

	Frequency	Percent
0-24hrs	66	85.7
24-48hrs	4	5.2
>48hrs	7	9.1
Total	77	100.0

Figure 18: Graph showing Distribution of subjects according to ICU stay
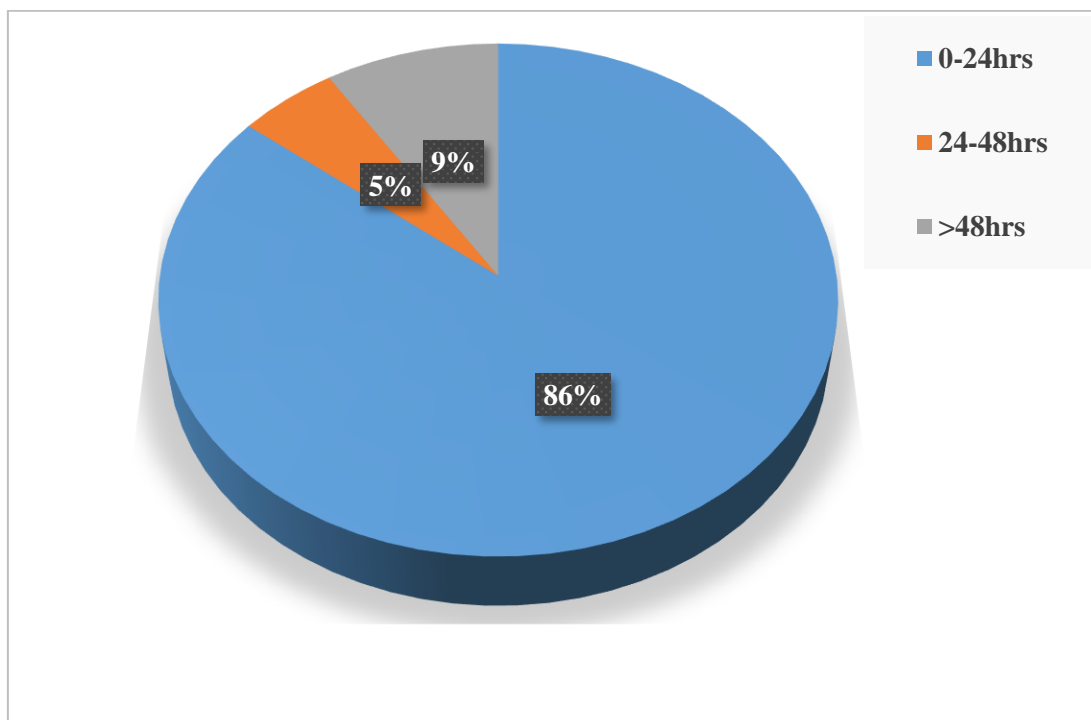
In our study patients with 0-24hrs of ICU stay were 66 (85.7%), patients with 24-48hrs of ICU stay were 4 (5.2%), patients with >48hrs of ICU stay were 7 (9.1%).

Table 6: Frequency Distribution of various complications.

	Frequency	Percent
Flap necrosis	9	11.7
Wound gaping	14	18.2
Flap gaping	15	19.5
Flap infection	6	7.8
Orocutaneous fistula	28	36.4
Others	10	12.9

Figure 19: Graph showing Frequency Distribution of various complications
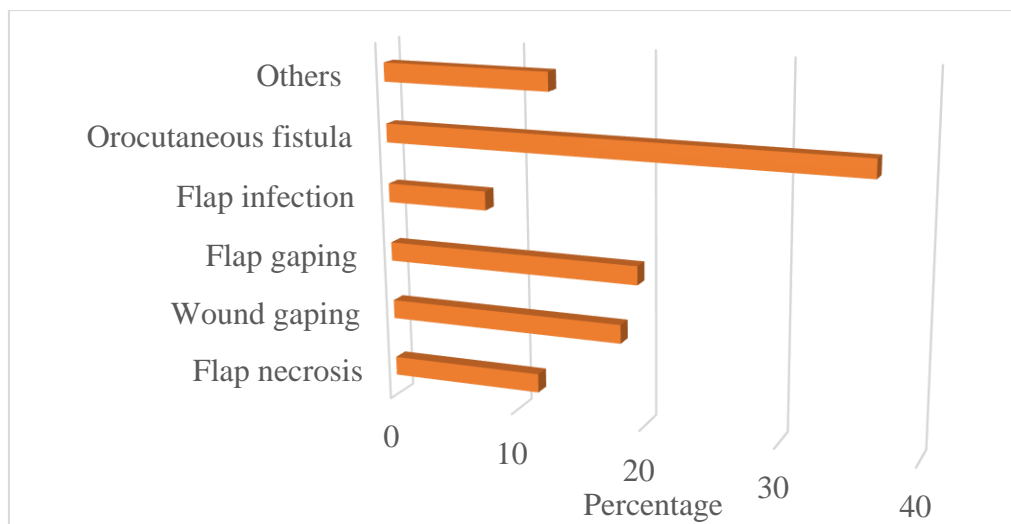
In our study patients with flap necrosis were 9 (11.7%), patients with wound gaping were 14 (18.2%), patients with flap gaping were 15 (19.5%), patients with flap infection were 6 (7.8%), patients with orocutaneous fistula were 28 (36.4%) and patients with other complications(electrolyte imbalance, lung infection, vascular blowout) were 10 (12.9%).

Table 7: Distribution of subjects according to complication

	Frequency	Percent
Absent	34	44.2
Present	43	55.8
Total	77	100.0

Figure 20: Graph showing Distribution of subjects according to complication
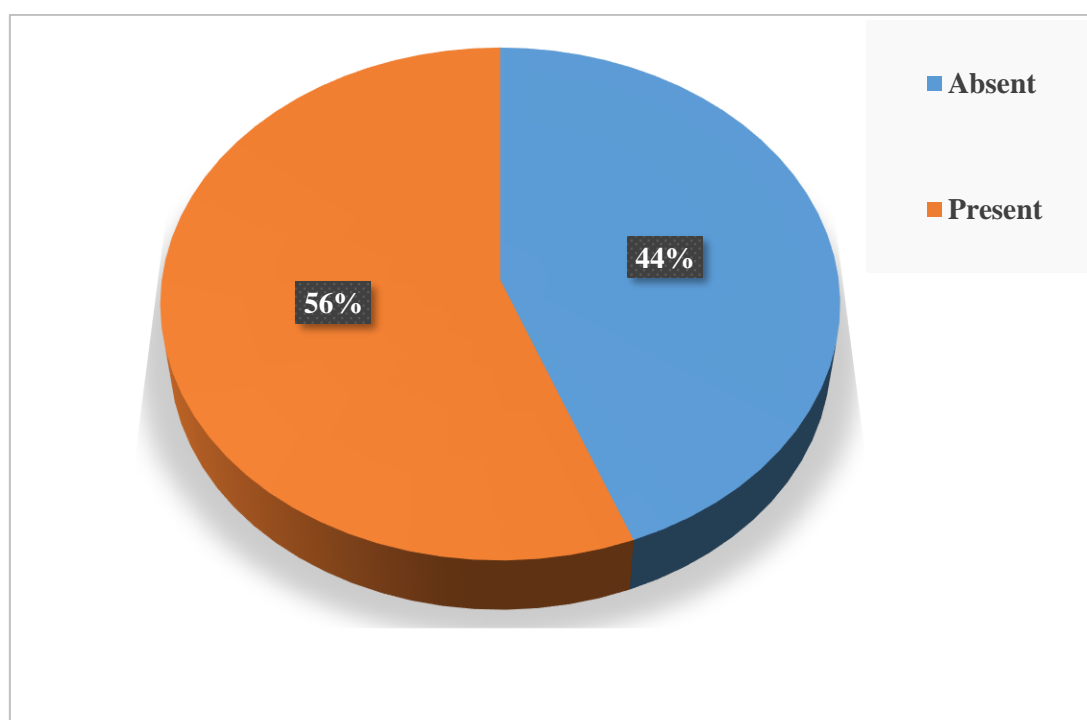
Table 8: Distribution of subjects according to type of adjuvant treatment

	Frequency	Percent
CT	2	2.6
CT/RT	9	11.7
RT	53	68.8
NO	7	9.1
REFUSED	6	7.8
Total	77	100.0

Figure 21: Graph showing Distribution of subjects according to type of adjuvant treatment
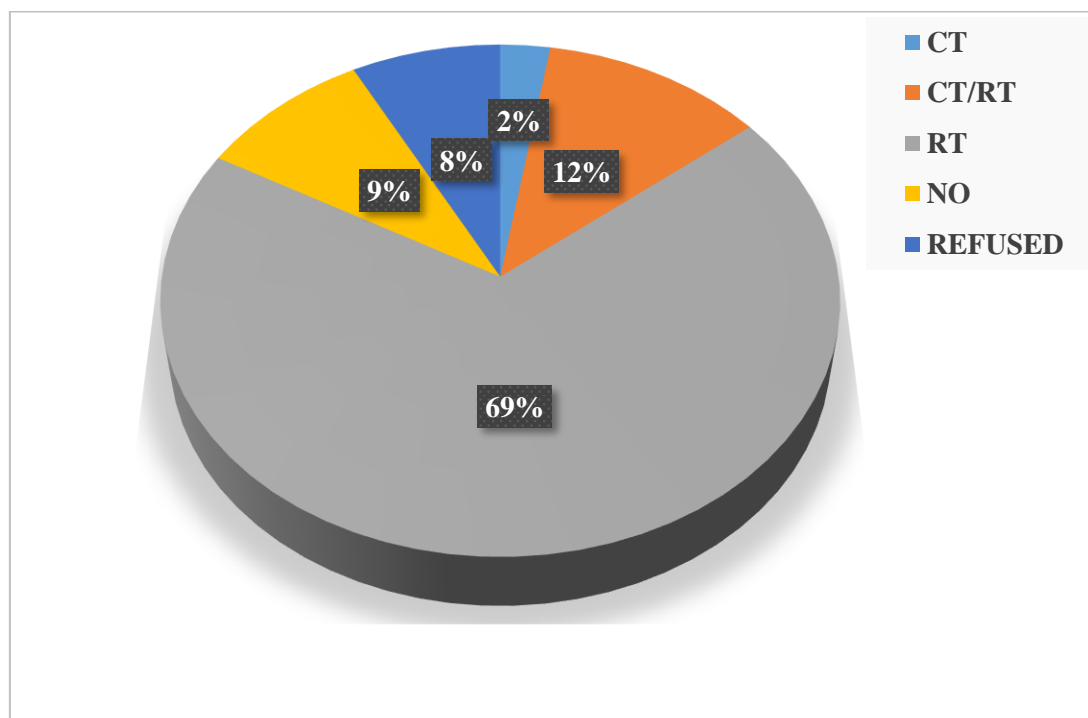
In our study post-operatively 53 patients (68.8%) underwent RT, 9 patients (11.7%) underwent CT+RT, 2 patients (2.6%) underwent only CT, 7 (9.1%) patients did not require adjuvant treatment, 6 patients (7.8%) refused for any adjuvant treatment.

Table 9: Distribution of subjects according to delay in adjuvant treatment

	Frequency
<7days	5
>7days	3

10.3% of the subjects had delay in adjuvant treatment.

Figure 22: Graph showing Distribution of subjects according to delay in days
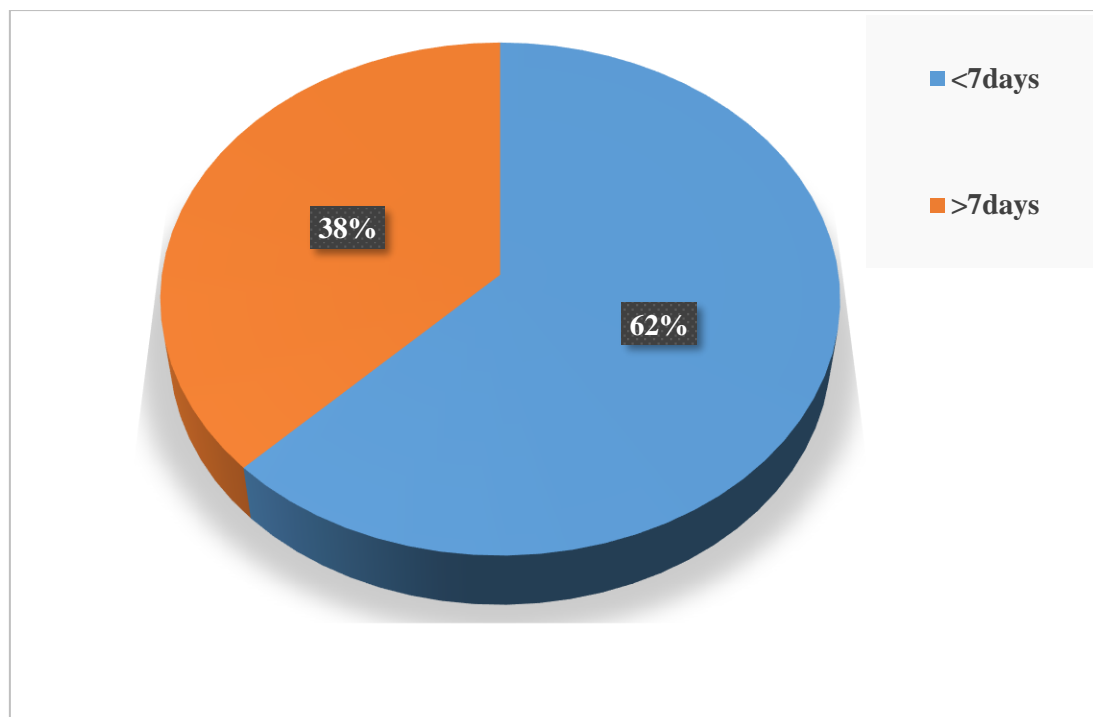
In our study only 10.3% of patients had delay in adjuvant treatment among them 5 people had a delay of < 7 days and 3 patients had a delay of ≥7days.

Table 10: Distribution of subjects according to hospital stay

	Frequency	Percent
1-2months	35	45.5
2-3months	31	40.3
>3months	11	14.3
Total	77	100.0

Figure 23: Graph showing Distribution of subjects according to hospital stay
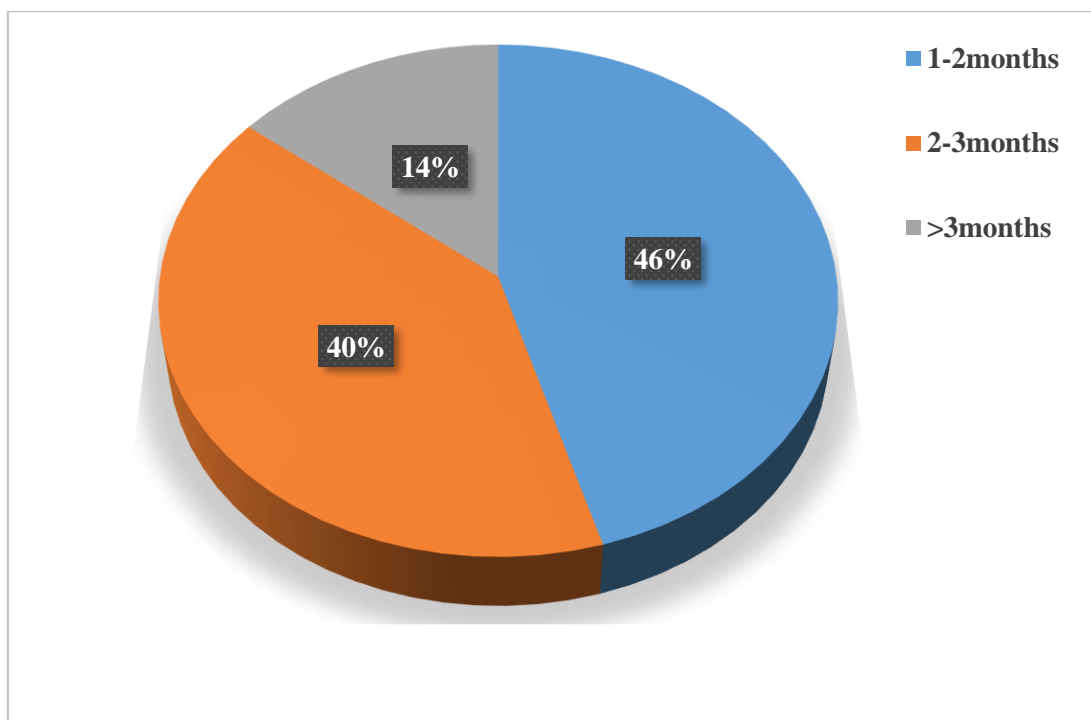
In our study patients with 1-2 months of hospital stay were 35 (45.5%), patients with 2-3 months of hospital stay were 31 (40.3%), patients with >3 months of hospital stay were 11 (14.3%).

Table 11: Distribution of subjects according to Outcome

	Frequency	Percent
bedridden	1	1.3
needs assistance	8	10.4
Needs minimal assistance	1	1.3
Perform activities on his own	67	87.0

Figure 24: Graph showing Distribution of subjects according to Outcome
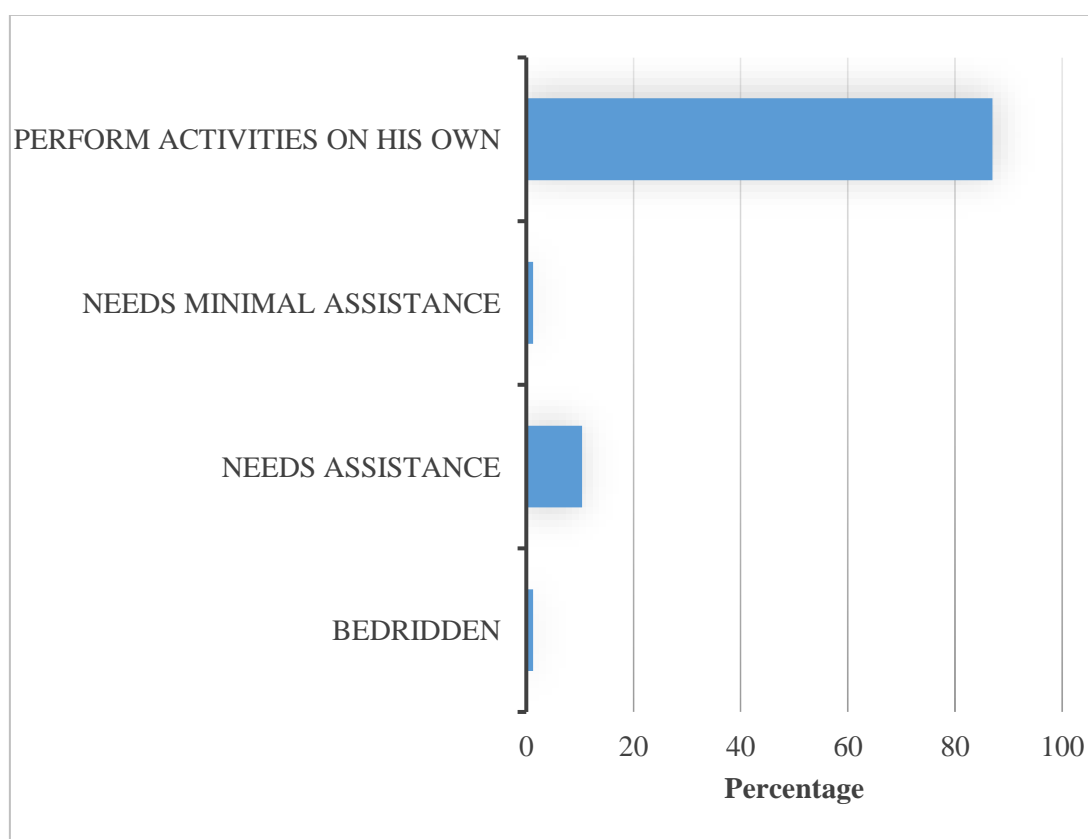
In our study outcome of the patient after treatment were documented – 67 patients (87%) were able to perform activities individually, 8 patients (10.4%) needed assistance, 1 patient (1.3%) needed minimal assistance, 1 patient (1.3%) was bedridden.

Figure 25: ROC curve for APACHE II in predicting complication
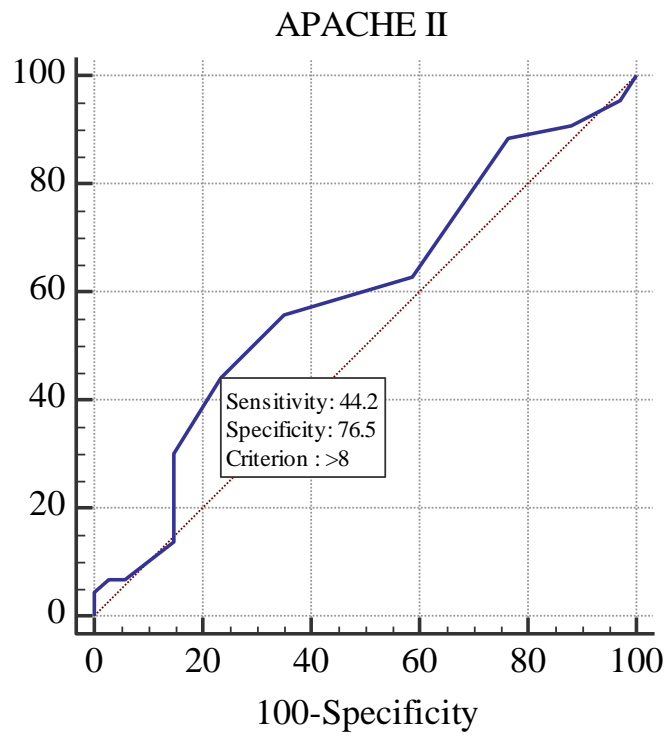
Table 12: Sensitivity, Specificity, PPV, NPV for APACHE II in predicting complication

Cut off	Sensitivity	Specificity	PPV	NPV
>8	44.19	76.47	70.4	52.0

Figure 26: ROC curve for EPASS in predicting complication

EPASS

Sensitivity: 20.9
Specificity: 100.0
Criterion : >5.51
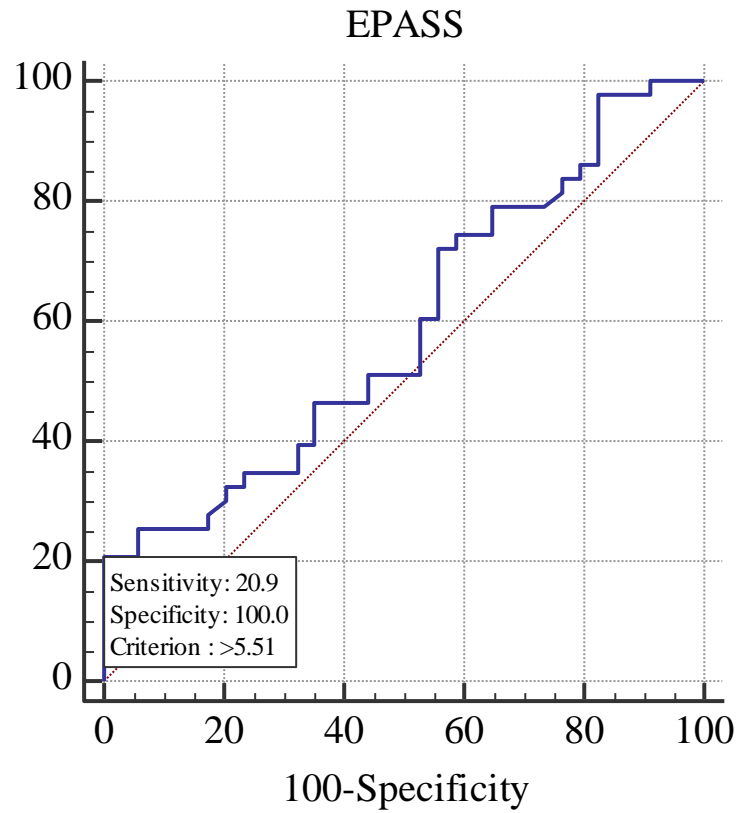
100-Specificity

Table 13: Sensitivity, Specificity, PPV, NPV for EPASS in predicting complication

Cut off	Sensitivity	Specificity	PPV	NPV
>5.51	20.9	100	100	50

Figure 27: ROC curve for POSSUM in predicting complication

POSSUM

Sensitivity: 76.7
Specificity: 38.2
Criterion : >32
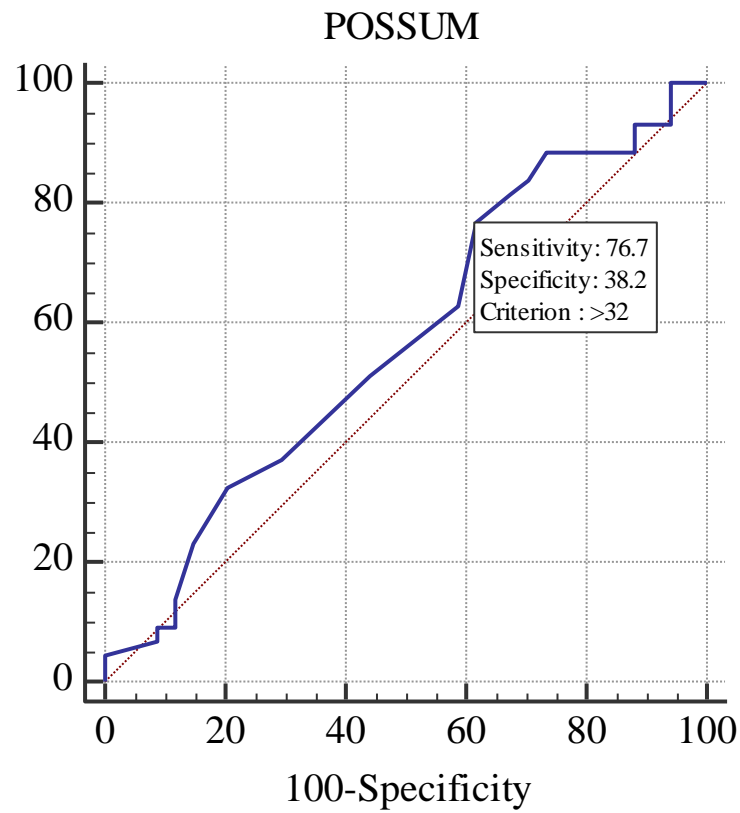
100-Specificity

Table 14: Sensitivity, Specificity, PPV, NPV for POSSUM in predicting complication

Cut off	Sensitivity	Specificity	PPV	NPV
>32	76.7	38.2	61.1	56.5

Figure 28: Comparison ROC curve of APACHE II , EPASS and POSSUM in predicting complication
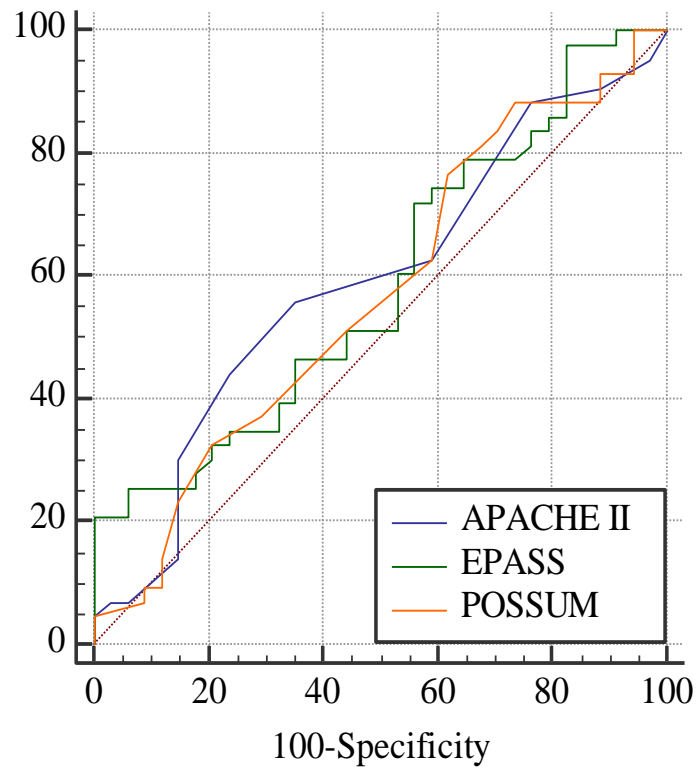
Table 15: Comparison ROC curve of APACHE II , EPASS and POSSUM in predicting complication

	AUC	95% CI
APACHE_II	0.594	0.476 to 0.704
EPASS	0.590	0.472 to 0.700
POSSUM	0.569	0.452 to 0.682

APACHE II score had better AUC then other two score, EPASS had better AUC then other POSSUM in predicting complication.

Overall in predicting complication APACHE II score > EPASS > POSSUM.

Table 16: Comparison of APACHE II , EPASS and POSSUM according to complication

	Absent		Present		P Value
	Mean	SD	Mean	SD	
APACHE II	7.18	2.393	8.00	2.655	0.162
EPASS	3.86	1.33	4.86	2.87	0.066
POSSUM	33.21	4.953	34.63	4.870	0.212

There was no statistical significance found between complications and three score

(APACHE II , EPASS and POSSUM)

Table 17: Comparison of APACHE II , EPASS and POSSUM according to ICU stay

	0-24hrs		24-48hrs		>48hrs		P Value
	Mean	SD			Mean	SD	
APACHE II	7.4	2.3	9.0	3.8	9.1	3.5	0.125
EPASS	4.2	1.9	4.5	1.9	6.5	4.7	**0.047**
POSSUM	33.5	4.9	40.3	4.8	35.0	2.6	**0.023**

No statistical significance found between ICU stay and APACHE II.

Statistical significance observed between ICU stay and EPASS.

Statistical significance observed between ICU stay and POSSUM

Table 18: Comparison of APACHE II, EPASS and POSSUM according to hospital stay

	1-10days		11-20days		>20days		P Value
	Mean	SD			Mean	SD	
APACHE II	7.9	2.8	7.7	2.5	6.7	2.1	0.439
EPASS	3.8	1.3	4.7	2.6	5.7	3.5	0.057
POSSUM	33.0	4.7	34.3	5.2	36.5	4.4	0.118

No statistical significance found between hospital stay and APACHE II.

No statistical significance found between hospital stay and EPASS.

No statistical significance found between hospital stay and POSSUM

DISCUSSION

DISCUSSION

Cancer is one of the most feared illnesses in the world. The main cause of the rising cancer incidence is ascribed to changes in lifestyle each year.[45] The cancer profile varies across the globe, and an epidemiological study will highlight the most prevalent malignancies in specific population segments as well as the associated risk factors.[46]

In a study done in Kolar in SDUMC about different types of cancer presentations, it has been documented that the most common site for cancer is oral cavity which was equal among both genders and histopathologically most of them were Squamous Cell Carcinoma.

Large number of oral cancers in Kolar are attributed mainly to the addiction of population to tobacco quid, or betel leaf with tobacco, areca nut etc, along with alcohol and smoking.[9]

Operable oral cancer patients undergo surgery (Resection of the tumour along with neck node clearance and reconstruction). Post-operatively patient may or may not need adjuvant treatment(radiotherapy/chemotherapy) as a part of completion of treatment. Hence the estimation of outcome of surgery is of utmost importance in disease stratification and subsequent management. Several scoring systems were formulated in order to predict outcome of surgery with regard to recovery.

ASA (American society of Anesthesiology) is one of the oldest and widely used scoring system to predict perioperative morbidity and mortality.[47] In latest years improvement in new statistical methods have led to identification of new indices to predict outcome of surgery.[10] However there are only few studies in predicting the outcome of oral cavity cancer surgery.[11]

In one study conducted by De Cássia et al, in 2003, preoperative assessment of 430 patients undergoing surgery for oral cancer was done using three scoring system – APACHE II, POSSUM and ASA to predict the outcome of surgery. Then they compared the above mentioned scoring system among each other in order to find out which one is more accurate in predicting the outcome of surgery. They found positive correlation between clinical TNM stage, type of surgical procedure and occurrence of post-operative complications. Overall mortality in perioperative period was 2.6%(n=14). The postoperative morbidity was 58.9% and they concluded that APACHE II and POSSUM performed well in predicting outcome of surgery. [10]

In another study conducted by Ishihata K et al in 2018, they have compared two scoring systems namely EPASS and APACHE II in predicting the outcome of 30 patients undergoing oral cancer surgery. They concluded by proving both the scoring systems were found equally accurate in predicting outcome of surgery.[11]

However there is no study comparing the reliability and accuracy of all three scoring systems (APACHE2, EPASS, POSSUM) in patients undergoing major oral cancer surgery. Therefore in this study we compared the reliability and accuracy of the above three scoring systems in predicting the outcome of surgery in our patients who are quite different in built, nutrition, addictions and extent of disease compared to western countries.

In our study we have preoperatively assessed 77 patients hailing from in and around Kolar district, who underwent surgery for oral cancer using three scoring systems namely APACHE II, EPASS and POSSUM. Patients with tumor staging T3 and T4 were included in this study in contrast to other study where patients with tumor staging T1-T4 were included.[10]

In our study females outnumbered males which is in contrast to literature[48,49], the reason for high prevalence of oral cancer among females in this region can be explained by addiction to tobacco quid among females. This addiction to tobacco quid starts early in life(around 20-25 years age). The male population in this region are more addicted to smoking. Lack of awareness, poverty, and disregard for the female population can be blamed for the advanced stage of disease in most patients in this region.

In our study 40.3% of patients were in the age group of more than 60 years, 24.7% and 27.3% of patients were in the age group 41-50 years and 51-60 years respectively, very low percentage of patients were below 40 years of age group. The mean age in our study was 56.75 years which was in accordance with literature.[10,50]

Among oral cavity subsite involved most common subsites were Buccal Mucosa and gingiva-buccal sulcus(mostly lower GBS). This can be attributed to the typical method of chewing the tobacco and beetle nut quid on one side of cheek throughout the day.

This causes pressure and increased local exposure to carcinogen over the buccal mucosa and gingiva-buccal sulcus areas. Most of the patients present in T4 stage, this can be attributed to poverty, lack of knowledge and seriousness about the consequences of delayed treatment of cancer among the population in Kolar.

All patients pre-operatively underwent hematological and radiological evaluation(contrast enhanced computed tomography of head and neck region), following which three scores were calculated prior and post surgery. Post operatively the following variables were documented – duration of ICU stay, local complications (like flap necrosis, wound gaping, flap gaping, flap infection, oro-cutaneous fistula and other complications which includes electrolyte imbalance cardio-pulmonary problems etc.), type of adjuvant treatment, delay and reason for delay in adjuvant treatment, total duration of hospital stay and outcome of treatment.

85.7% of patients had one day of ICU stay, only 11 patients had an ICU stay of more than one day among which 6 patients had poor respiratory effort leading to delay in weaning off the ventilator, 1 patient had developed hypoxic brain injury because of inadequate respiratory effort in the ward and rest 4 patients were kept for observation for 1 or 2 days in ICU. Regarding local post operative complications 36.4% patients had oro-cutaneous fistula whereas in literature it is 16.2%[10] this could be attributed to negligence by the patient to do proper oral care at frequent intervals , 19.5% patients had flap gaping, 11.7% had flap necrosis and 7.8% had flap infection whereas in literature it is 26.2%, 22.1% and 32.5% respectively[10] this could be attributed to better surgical techniques evolved in recent years, better ICU protocols in our institute and good immunity among our patients. 18.2% patients had wound gaping which was a minor complication. Wound gaping and oro-cutaneous fistula were managed conservatively using daily dressing and antiseptic mouth gargles whereas in flap gaping 4 patients needed re-suturing while the rest where managed conservatively. Other complications which includes electrolyte imbalance cardio-pulmonary problems etc were 12.9%, in literature it was 25.7%[10]which could also be attributed to good immunity among the population and standard ICU protocols.

Regarding post-operative complications 9 patients had flap necrosis with score ranging from 6-13 for APACHE II(mean-9), 2.48-16.95 for EPASS(mean-6.14) and 32-38 for POSSUM(mean-35). For flap infection scores ranged from 7-10 for APACHE II(mean-8), 3.3-6.7 for EPASS(mean-5.54) and 36-46 for POSSUM(mean-38). For wound gaping scores ranged from 6-13 for APACHE II(mean-8), 2.89-16.95 for EPASS(mean-6.3) and 25-39 for POSSUM(mean-34). For flap gaping scores ranged from 3-13 for APACHE II(mean-8), 2.11-16.95 for EPASS(mean-5.05) and 25-42 for POSSUM(mean-32). For oro-cutaneous fistula scores ranged from 4-14 for APACHE II(mean-8), 2.11-6.5 for EPASS(mean-4.3) and 27-46 for POSSUM(mean-34).

On the whole the mean APACHE II score in patients without complications is 7.18(2.39), in literature it is 6.65(3.55), mean APACHE II score for patients with complications is 8(2.65) which is in accordance with literature – 8.38(4.17). Mean POSSUM score in patients without complications is 33.21(4.95), in literature it is 26.15(4.86), mean POSSUM score for patients with complications is 34.63(4.87), in literature – 28.86(5.67).[10] Mean EPASS score with and without complications were 4.86(2.87) and 3.86(1.33) respectively.

APACHE II with score cut off >8 had sensitivity of 44.19, specificity 76.47, PPV- 70.4 and NPV-52. EPASS with score cut off >5.51 had sensitivity of 20.9, specificity 100, PPV- 100 and NPV-50. POSSUM with score cut off >32 had sensitivity of 76.7, specificity 38.2, PPV-61.1 and NPV-56.5.

However there was no statistical significance found between the post-operative complications and the three scores, APACHE II (p-0.162), EPASS(p-0.066) and POSSSUM(p-0.212). With regards to ICU stay, APACHE II was not statistically significant(p-0.125) whereas EPASS(p-0.047) and POSSUM(p-0.023) were statistically significant.

Post-operatively after the wound heals patients received adjuvant treatment, among the 77 patients, 6 patients refused for treatment, 7 patients did not require any adjuvant treatment.

Among the patients who received adjuvant treatment 68.8% patients received only RT, 11.7% patients received chemoradiotherapy, 2 patients got only chemotherapy. Patient who had close tumor margins, positive lymph nodes and depth of invasion > 10mm in histopathological evaluation received chemoradiation. 2 patients who got only chemotherapy was because they both had tumor recurrence in contralateral lymph node in the neck. In this study we have taken 4-6 weeks as the duration after surgery for starting adjuvant treatment. Only 10.3% of patients had delay in starting adjuvant treatment which was because of delayed wound healing and delayed recovery from surgery.

The total duration of hospital stay was 1-2 months in 45.5%, 2-3 months in 40.3% and >3 months in 14.3% whereas in literature average duration was 78.6 ± 46.2 days[11] the reason could be attributed to delayed wound healing before starting adjuvant treatment and prolonged course of adjuvant treatment due to its possible side effects. Between hospital stay and the three scoring systems, there was no statistically significant difference observed. Even so, the study's overall result was encouraging as 87% of the patients could perform activities on their own.

APACHE II score (area under curve - 0.594) exhibited a stronger predictive ability than EPASS (area under curve - 0.590), and POSSUM(area under curve – 0.569), according to the ROC curve study for predicting post-operative outcome.

LIMITATIONS OF THE STUDY:

1. Relatively smaller sample size .
2. Majority of patients having locally advanced diseases hence comparison with early disease was not balanced.
3. Shorter follow up
4. Single institutional study

FUTURE SCOPE OF STUDY:

1. These scoring systems in future can be used to pre-operatively assess all patients undergoing oral cancer surgery and these scores can be used to improve quality of surgical performance and quality of post-op care.
2. Taking this study as reference new scoring systems can be developed for predicting the outcome of Indian patients undergoing oral cancer surgery.

SUMMARY

SUMMARY

Oral malignancies are one of the most common non communicable diseases in many parts of the globe. India accounts for fifth position in existence of oral cavity cancer which is because of high incidence of tobacco and betel leaf and nut quid chewing. Occurrence of oral cavity malignancies in Kolar district in Karnataka is high. Majority of the patients in Kolar present as locally advanced cancers - stage T_3 and T_4, requiring major and sometimes mutilating surgeries and reconstruction.

OBJECTIVES:

1. To assess patients undergoing oral cancer surgery using APACHE 2, EPASS and POSSUM scoring systems preoperatively.
2. To compare the accuracy of the above mentioned scoring systems in predicting the outcome of surgery with regard to wound healing, post-operative complications and duration of ICU and hospital stay.

In this prospective observational study, 77 biopsy proven oral cancer patients planned for major surgery at R.L.J.H and Research Centre Tamaka, Kolar from January 2021 to July 2022 after fulfilling the inclusion criteria were included. Patients were scored by each of these scoring systems (APACHE II, EPASS and POSSUM) preoperatively and the surgical outcome with regards to wound healing, post-op complications, and length of ICU and hospital stay were documented. The scoring systems were then compared among each other to find the most suitable scoring system for our population.

Follow up period- minimum of 3 months.

In this study, we had 70% of patients as female, mostly in the age group >60 years. The mc site involved was Buccal mucosa and lower GBS due to the consumption of tobacco quid in those areas overnight.

The post-operative complication, duration of ICU stay, type of adjuvant treatment, delay in adjuvant treatment, total duration of hospital stay and overall outcome of treatment were documented, the scores were then compared among each other on the basis of these documented parameters.

There was no statistical significance found between the post-operative complications and the three scores. With regards to ICU stay, APACHE II(p-0.125) was not statistically significant whereas EPASS(p-0.047) and POSSUM(0.023) were statistically significant.

However APACHE II score (AUC-0.594) had a better AUC curve than EPASS score (AUC-0.590) and POSSUM score (AUC-0.569).

CONCLUSION

CONCLUSION

1. In our study most of patients were elderly females which can be attributed to their addiction to tobacco or betel nut quid chewing.

2. Majority of patients present as locally advanced disease due to late presentation owing to poverty and lack of awareness.

3. We have analyzed the efficacy of three scoring systems namely APACHE II , EPASS and POSSUM in predicting the surgical outcome, hospital stay, post-operative complications.

4. All three scoring systems were able to predict the post-operative outcome for patients and there was statistical significance found between ICU stay and EPASS and POSSUM scores.

5. However there was no statistical significance between post-op complications and total duration of hospital stay with respect to the three scoring systems.

6. AUC was better in APACHE II than the other two scoring systems in predicting surgical outcome. Hence APACHE II is slightly better compared to other two scoring systems in predicting post-operative outcome.

7. Larger multi-institutional study incorporating various stages of the disease maybe desirable to have definite outcomes and device a study more reliable for our population

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BIBLIOGRAPHY

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ANNEXURES

ANNEXURES

PROFORMA:

DATE:

S.NO.	COMPONENTS	VARIABLES
1.	PATIENT NAME	
2.	AGE	
3.	UHID	
4.	DIAGNOSIS	
5.	PLAN	
6.	DURATION OF SURGERY	
7.	INTRA-OPERATIVE EVENTS IF ANY	

APACHE 2 SCORING SYSTEM

	COMPONENTS	VALUES
1	AGE (YEARS)	
2	MEAN BLOOD PRESSURE (mm hg)	
3	HEART RATE (BEATS/MINUTE)	
4	RESPIRATORY RATE (BREATHS/MIN)	
5	ARTERIAL PH	
6	FiO2	
7	SERUM SODIUM (mEq/L)	
8	SERUM POTTASIUM (mEq/L)	
9	SERUM CREATININE (mg/dl)	
10	HAEMATOCRIT (gm%)	
11	WBC (x10^3 micro litre)	
12	GCS	
13	TEMPRATURE (DEGREE CELCIUS)	
14	ELECTIVE / EMERGENCY SURGERY	

EPASS SCORING SYSTEM

	COMPONENTS	VALUES
1	AGE (YEARS)	
2	SEVERE HEART DISEASE +/-	
3	SEVERE PULMONARY DISEASE +/-	
4	DIABETES MELLITUS +/-	
5	PERFORMANCE STATUS INDEX (0-4)	
6	ASA CLASSIFICATION (1-5)	
7	BLOOD LOSS(ml)/BODY WEIGHT(kg)	
8	OPERATION TIME (HOURS)	
9	SKIN INCISION TYPE	

POSSUM SCORING SYSTEM

	COMPONENTS	VALUES
1	AGE (YEARS)	
2	CARDIAC FAILURE +/-	
3	CHEST RADIOGRAPHY (CARDIOMEGALY +/-)	
4	CHEST RADIOGRAPHY (LUNG)	
5	RESPIRATORY HISTORY (DYSPNEA +/-)	
6	MEAN SYSTOLIC BP (mm hg)	
7	PULSE RATE (beats/min)	
8	SERUM SODIUM (mEq/L)	
9	SERUM POTTASIUM (mEq/L)	

10	SERUM UREA (mg/dl)	
11	HAEMOGLOBIN (g/dl)	
12	WBC (x10^3 micro litre)	
13	GCS	
14	ECG	
15	OPERATIVE SEVERITY	
16	ELECTIVE / EMERGENCY SURGERY	
17	TOTAL BLOOD LOSS (ml)	
18	NUMBER OF PROCEDURES	
19	CARCINOMA STAGE	

POST OPERATIVE COMPLICATIONS

S.NO.	COMPLICATIONS	+/- DURATION
1	TOTAL LENGTH OF ICU STAY (days)	
2	FLAP NECROSIS	
3	FLAP INFECTION	
4	FLAP FAILURE	
5	OROCUTANEOUS FISTULA	
6	METABOLIC DERANGEMENTS	
7	TYPE OF ADJUVANT TREATMENT	

8	DELAY IN START OF ADJUVANT TREATMENT (days)	
9	TOTAL LENGTH OF HOSPITAL STAY (days)	
10	OTHER COMPLICATIONS IF ANY:	
11	FOLLOW UP AFTER 1 MONTH	
12	FOLLOW UP AFTER 3rd MONTH	
13	STATUS AT LAST FOLLOW UP AND DATE OF LAST FOLLOW UP.	

Name of the study - "Comparison of Acute Physiology and Chronic Health Evaluation (APACHE2) Physiological and Operative Severity Score for Enumeration of Mortality and Morbidity (POSSUM) and Estimation of Physiologic Ability and Surgical Stress (EPASS) scoring systems in preoperative evaluation of patients planned for oral cancer surgery"

I have read the foregoing information, or it has been read to me. I have had the opportunity to

ask questions about it and any questions that I have asked have been answered to my satisfaction.

I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____ Date _____

For illiterate -

I have witnessed the accurate reading of the consent form to the potential participant, and the

individual has had the opportunity to ask questions. I confirm that the individual has given

consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____ Date _____

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant with the best of

my ability. I confirm that the participant was given an opportunity to ask questions about the

study, and all the questions asked by the participant have been answered correctly and to the

best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher taking the consent_____

Signature of Researcher taking the consent_____

Date_____

Principal Investigator's Name : Dr. S.Akshaya

Mobile Number : 9444475453   Email Id : akshayarajan156@gmail.

ಶ್ರೀ ದೇವರಾಜ್ ಅರಸ್ ಉನ್ನತ ಶಿಕ್ಷಣ ಮತ್ತುಸಂಶೋಧನಾ ಸಂಸ್ಥೆ,

ಟಮಕ, ಕೋಲಾರ - 563101.

ತಿಳಿವಳಿಕ ಸಮ್ಮತಿ ನಮೂನೆ

ಅಧ್ಯಯನದ ಹೆಸರು – "ತೀವ್ರವಾದ ಶರೀರವಿಜ್ಞಾನ ಮತ್ತುದೀರ್ಘಕಾಲದ ಆರೋಗ್ಯ ಮೌಲ್ಯಮಾಪನ (ಎಪಿಎಚ್ಇ 2) ಮರಣ ಮತ್ತು ಅಸವಸ್ಥತೆ (ಪ್ರೋಸಸಮ್) ಮತ್ತುದೈಹಿಕ ಸಾಮರ್ಥ್ಯಫ ಮತ್ತುಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ಒತ್ತಡದ ಅಂದಾಡು (ಇಪಾಸ್) ಸೆ ಕೋರಿಂಗ್ ವ್ಯವಸ್ಥೆಗಳ ಅಂದಾಜುಗಾಗಿ ಶಾರೀರಕ ಮತ್ತುಆಪರೋಟಿವ್ ತೀವ್ರತೆಯ ಸೆ ಕೋರ್ ಮೌಖಿಕ ಕಾಯನಸರ್ ಶಸ್ತ್ರಚಿಕಿತೆಸಗಾಗಿ "

ನಾನು ಮೇಲಿನ ಮಾಹಿತಿಯನ್ನು ಓದಿದ್ದೇನೆ, ಅರ್ಥವಾ ಅದನ್ನು ನನಗೆ ಓದಲಾಗಿದೆ. ನನಗೆ ಅವಕಾಶ ಸಿಕಿದ ಅದರ ಬಗೆಗೆಪರಶ್ನೆಗಳನ್ನು ಕೇಳಿ ಮತ್ತುನಾನು ಕೇಳಿದ ಯಾವುದೇ ಪರಶ್ನೆಗಳಿಗೆ ನನ್ನ ತೃಪ್ತಿಗೆ ಉತ್ತರಿಸಲಾಗಿದೆ. ಈ ಸಂಶೋಧನೆಯಲ್ಲಿಪಾಲ್ಗೊಳ್ಳಲು ನಾನು ಸವಯಂಪ್ರೇರಣೆಯಿಂದ ಒಪ್ಪುತ್ತೇನೆ.

ಭಾಗ್ಗಿ ಸುವ್ಯ ಮುದ್ರಣ ಹೆಸರು _____

ಭಾಗ್ಗಿ ಸುವ್ಯ ಸಹಿ _____ ದಿನಾಂಕ _____

ಅನಕ್ಷರಸ್ಥರಿಗೆ –

ಸಂಭಾವ್ಯ ಭಾಗ್ಗಿ ಸುವ್ಯಿಗೆ ಒಪ್ಪಿಗೆಯ ರ ಪವ್ಯು ನಿಖರವಾಗಿ ಓದುವ್ಉದಕ್ಕೆ ನಾನು ಸಾಕ್ಷಿಯಾಗಿದ್ದೇನೆ ಮತ್ತು ವ್ಯಕ್ತಿಯು ಪರಶ್ನೆಗಳನ್ನು ಕೇಳುವ ಅವಕಾಶವನ್ನು ಹೊಂದಿದೆ. ವ್ಯಕ್ತಿಯು ನೋಡಿದಾದನೆ ಎಂದು ನಾನು ಖಚಿತ್ತಪಡಿಸುತ್ತೇನೆ ಮುಕುವಾಗಿ ಒಪ್ಪಿಗೆ.

ಸಾಕ್ಷಿಯ ಮುದ್ರಣ ಹೆಸರು _____ ಮತ್ತುಭಾಗ್ಗಿ ಸುವ್ಯ ಹೆಬೆಟ್ಟೆರಳು ಮುದ್ರಣ

ಸಾಕ್ಷಿಯ ಸಹಿ _____ ದಿನಾಂಕ _____

ಒಪ್ಪಿಗೆ ಪಡೆಯುವ್ ಸಂಶೋಧ / ವ್ಯಕ್ತಿಯ ಹೇಳಿಕೆ

ನಾನು ಸಮರ್ಥ್ಯಫಶ್ದೆಂದಿಗೆ ಸಂಭಾವ್ಯ ಭಾಗ್ಗಿ ಸುವ್ಯಗೆ ಮಾಹಿತಿ ಹಾಳೆಯನ್ನು ನಾನು ನಿಖರವಾಗಿ ಓದಿದ್ದೇನೆ. ಭಾಗ್ಗಿ ಸುವ್ಯಗೆ ಅಧ್ಯಯನದ ಬಗೆಗೆಪರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ಅವ್ಯಾಶ ನೋಡಲಾಗಿದೆ ಎಂದು ನಾನು ಖಚಿತ್ತಪಡಿಸುತ್ತೇನೆ, ಮತ್ತುಭಾಗ್ಗಿ ಸುವ್ಯ ಕೇಳಿದ ಎಲಾಪರಶ್ನೆಗಿಗೆ ಸರಯಾಗಿ ಉತ್ತರಿಸಲಾಗಿದೆ ಮತ್ತುನನ್ನು ಸಾಮರ್ಥ್ಯಫಕೆಕ ತಕ್ಕಂತೆ. ಒಪ್ಪಿಗೆ ನೋಡುವಂತ ವ್ಯಕ್ತಿಯನ್ನು ಒತ್ತಯಿಸಲಾಗಿಲಿ ಮತ್ತುಒಪ್ಪಿಗೆಯನ್ನು ಮುಕುವಾಗಿ ಮತ್ತುಸವಯಂಪ್ರೇರಣೆಯಿಂದ ನೋಡಲಾಗಿದೆ ಎಂದು ನಾನು ಖಚಿತ್ತಪಡಿಸುತ್ತೇನೆ. ಭಾಗ್ಗಿ ಸುವ್ಯಗೆ ಈ ಐಸಿಎಫ್ ನಕಲನ್ನು ಒದಗಿಸಲಾಗಿದೆ.

ಒಪ್ಪಿಗೆ ತೆಗೆದುಕೊಳ್ಳುವ್ ಸಂಶೋಧಕರ ಮುದ್ರಣ ಹೆಸರು _____

ಒಪ್ಪಿಗೆಯನ್ನು ತೆಗೆದುಕೆ ಳುವ್ ಸಂಶೋಧಕರ ಸಹಿ _____

ದಿನಾಂಕ _____

ಪ್ರಧಾನ ತ್ನಿಖಾಧಿಕಾರ ಹೆಸರು: ಡಾ.ಎಸ್.ಅಕ್ಷಯ

ಮೊಬೈಲ್ ಸಂಖಿಯ: 9444475453

ಇಮೇಲ್ ಐಡಿ: akshayarajan156@gmail.com

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH,

TAMAKA, KOLAR - 563101.

PATIENT INFORMATION SHEET

Name of the study - "Comparison of Acute Physiology and Chronic Health Evaluation (APACHE2) Physiological and Operative Severity Score for Enumeration of Mortality and Morbidity (POSSUM) and Estimation of Physiologic Ability and Surgical Stress (EPASS) scoring systems in preoperative evaluation of patients planned for oral cancer surgery"

The purpose of this study is to identify a reliable and easy scoring system which can predict the outcome of surgery with regards to compare the efficacy of three scoring systems in evaluating the preoperative oral cancer patients included in our study.

We are inviting people diagnosed with oral cancer to take part in this study, however based on criteria list, eligible participants will be chosen among the interested ones. Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you agree to participate in this study, you will have to undergo 1.Chest radiography of heart and lungs 2.ECG 3.Blood investigations like WBC, serum urea, sodium, potassium . By participating in this research you will contribute in predicting the post-operative complications prior to the surgery and the study will not change the final outcome of your treatment. However, patients in the future may benefit as a result of knowledge gained from this study. You will not be charged extra for any of the procedures performed during the research study. Your participation in this study will not put you at any risk.

All information collected from you will be strictly confidential & will not be disclosed to any

outsider. This information collected will be used for research purpose. This information will not reveal your identity & this study have been reviewed by central ethical committee.

For any further clarification you are free to contact the Principal investigator, Dr S.Akshaya, mobile – 9444475453.

There is no compulsion to participate in this study, further you are at the liberty to withdraw from the study at anytime if you wish to do so. Your treatment aspect will not be affected if you not wish to participate. The cost of the investigations will be borne by me. You are required to sign only if you voluntarily agree to participate in proposed study. This document will be stored in a safe locker at the Dept of Otorhinolaryngology and strict confidentiality will be maintained. A copy of this document will be given to you for your information.

Principal Investigator's Name : Dr S.Akshaya

Mobile Number : 9444475453

Email Id : akshayarajan156@gmail.com

ಶ್ರೀ ದೇವರಾಜ್ ಅರಸ್ ಉನ್ನತ ಶಿಕ್ಷಣ ಮತ್ತು ಸಂಶೋಧನಾ ಸಂಸ್ಥೆ,

ತಮಿಳ್ ಕ್ ಜಿಲ್ಲಾ - 563101.

ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆ

ಅಧ್ಯಯನದ ಹೆಸರು – "ತೋಪುವಾದ ಶರೀರಪ್ರತಿಷ್ಠಾನ ಮತ್ತು ಮುದ್ದೋಘ್ಚಕಾಲದ ಆರೋಗ್ಯ ಮೌಲ್ಯಮಾಪನ (ಎಪಿಎಚ್ಎ 2) ಮರಣ ಮತ್ತು ಅಸವಸ್ಥತೆ (ಪೋಸಮ್) ಮತ್ತುದೈಹಿಕ ಸಾಮರ್ಥ್ಯದ ಮತ್ತುಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ಒತ್ತಡದ ಅಂದಾಜು (ಇಪಾಸ್) ಸೆ ಕೋರಿಂಗ್ ವ್ಯವಸ್ಥೆಗಳ ಅಂದಾಜುಗಾಗಿ ಶಾರೀರಿಕ ಮತ್ತುಆಪರೇಟಿವ್ ತೀವ್ರತೆಯ ಸ್ಕೋರ್ ಮೌಖಿಕ ಕಾಯನಸರ್ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಗಾಗಿ " ಈ ಅಧ್ಯಯನದ ಉದ್ದೇಶವು ವಿಶ್ವಾಸಾರ್ಹ ಮತ್ತುಸುಲಭವಾದ ಸೆ ಕೋರಿಂಗ್ ವ್ಯವಸ್ಥೆಯನ್ನು ಗುರುತಿಸುವುದು, ಇದು ನಮ್ಮ ಅಧ್ಯಯನದಲ್ಲಿ ಒಳಗೆ ಇಂದಿರುವ ಪೂರ್ವಭಾವಿ ಬಾಯಿಯ ಕಾಯನಸರ್ ರೋಗಿಗಳನ್ನು ಮೌಲ್ಯಮಾಪನ ಮಾಡುವ ಫ್ಲು ಮ ರು ಸೆ ಕೋರಿಂಗ್ ವ್ಯವಸ್ಥೆಗಳ ಪರಿಣಾಮಕಾರತ್ವವನ್ನು ಕೆ ಹೋಲ್ಸಲು ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ಫಲಿತಾಂಶವನ್ನು can ಹೆಸಬಲಿದು. ಈ ಅಧ್ಯಯನದಲ್ಲಿಭಾಗ್ಗಿ ಸಲು ಮೌಖಿಕ ಕಾಯನಸರ್ ರೋಗಿಣಿಭಯ ಮಾಡಿದ ಜನರನ್ನು ನಾವು ಆಹ್ವಾನಿಸುತ್ತಿದ್ದೇವೆ, ಆದರ ಮಾನದಂಡ್ಗ ಪಟ್ಟಿಯ ಆಧಾರದ ಮೇಲೆ, ಆಸಕರಲ್ಲಿಅರ್ಥ ಭಾಗ್ಗಿ ಸುವ್ಯನು ಆಯ್ಕ ಮಾಡಲಾಗುತ್ತಿದೆ. ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ನಿಮ್ಮ ಭಾಗ್ಗಿ ಸುವಿಕೆ ಸಂಪೂಣರ್ಣವಾಗಿ ಸ್ವಯಂಪ್ರೇರ್ರೇತ್ವಾಗಿದೆ. ಭಾಗ್ಗಿ ಸಬೇಕೆ ಅರ್ಥವಾ ಬೋಡವೋ ಎಂಬುದು ನಿಮ್ಮ ಆಯ್ಕೆಯಾಗಿದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿಭಾಗ್ಗಿ ಸಲು ನೀವು ಒಪ್ಪಿದರೆ, ನೀವು ರಕ್ತಿದಯ ಮತ್ತುಶ್ವಾಸಕ ಸೋಧದ 1.ಕಿಸ್ ರೇಡಿಯೋಗ್ರಫಿಗೆ ಒಳಗಾಗ್ಗೋಕಾಗುತ್ತಿದೆ 2.ಇಸಿಜಿ 3. ಡಬ್ ಲ್ಯೂಬಿಸಿ, ಸೀರಮ್ ಯ ರೆಯಾ, ಸೋಡಿಯಂ, ಪೋಟ್ಯಾಸಿಯಮುಮತ್ರ ರಕುತ್ತಿಖಗೆ. ಈ ಸಂಶೋಧನೆಯಲ್ಲಿಭಾಗ್ಗಿ ಸುವ ಮ ಲ ಕ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಗೆ ಮುನ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ನಂತ್ರದ ತೆ ದಕುಗ್ನು in ಹಿಸಲು ನೀವು ಕೆ ಡುಗೆ ನೋಡುತ್ತ್ತೀರಾ ಮತ್ತುಅಧ್ಯಯನವು ನಿಮ್ಮ ಚಿಕಿತ್ಸೆಯ ಅಂತಿಮ ಫಲಿತಾಂಶವನ್ನು ಬದಲಾಯಿಸುವುದಿಲ್ಲ. ಆದಾಗ್ ಯ, ಈ ಅಧ್ಯಯನದಿಂದ ಪಡೆದ ಜ್ಞಾನದ ಪರಿಣಾಮವಾಗಿ ಭವಿಷ್ಯದಲ್ಲಿರ ರೋಗಿಗ್ಗಿ ಪರಯೋಜನ ಪಡೆಯಬರುದು. ಸಂಶೋಧ್ನಾ ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ನಿರ್ವಹಿಸುವ್ ಯಾವುದೋ ಕಾಯಫವಿಧಾನಗ್ಗಿ ನಿಮಗೆ ಹೆಚ್ಚುಂವ ಶುಲ್ಕ ವಿಧಿಸಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದಲ್ಲಿನಿಮ್ಮ ಭಾಗ್ಗಿ ಸುವಿಕೆಯು ನಿಮಗೆ ಯಾವುದೋ ಅಪಾಯವನ್ನುಂಟು ಮಾಡುವುದಿಲ್ಲ. ನಿಮ್ಮಿಂದ ಸಂಗ್ರಹಿಸಲಾದ ಎಲಾ ಮಾಹಿತಿಯ ಕಟ್ಟುನಿಟ್ಟಾಗಿ ಗೌಪ್ಯವಾಗಿರುತ್ತಿದೆ ಮತ್ತುಯಾವುದಕ ಕ ಬಹಿರಂಗ್ಗ್ಡಿಸುವುದಿಲ್ಲ ಹೆ ರಗಿನವ್ನು. ಸಂಗ್ರಹಿಸಿದ ಈ ಮಾಹಿತಿಯನ್ನು ಸಂಶ ೕಧ್ನಾ ಉದ್ದೇಶ್ಶಕಾಗಿ ಬಳಸಲಾಗುತ್ತಿದೆ. ಈ ಮಾಹಿತಿಯ ನಿಮ್ಮ ಗೌರುತ್ತು ಬಹಿರಂಗ್ಗ್ಡಿಸುವುದಿಲ್ಲಮತ್ತುಂಈ ಅಧ್ಯಯನವನ್ನು ಕೊಂದರ ನೈತಿಕ ಸಮಿತಿಯ ಪರಿಶೋಲಿಸಿದೆ. ಯಾವುದೋ ಹೆಚ್ಚಿನ ಸಿಡಿಸ್ೕಕರಣಕಾಗಿ ನೀವು ಪರಧಾನ ತ್ರಿಬಾಧಿಕಾರ ಡಾ.ಎಸ್.ಅಕ್ಷಾಯ, ಮೋಬೈಲ್ – 9444475453 ಅನ್ನು ಸಂಪಕಿಷಸಲು ಮುಕುರಾಗಿದ್ದೋರ. ಈ ಅಧ್ಯಯನದಲ್ಲಿಭಾಗ್ಗಿ ಸಲು ಯಾವುದೋ ಬಲವಂತ್ತಿಲ, ಮುಂದೆ ನೀವು ಹಿಂತೆಗೆದುಕ ಳುವ ಸಾವತಂತ್ರ್ಯೂದಲ್ಲಿದ್ದೋರ ನೀವು ಹಾಗೆ ಮಾಡಲು ಬಯಸಿದರೆ ಯಾವುದೋ ಸಮಯದಲ್ಲಿಅಧ್ಯಯನದಿಂದ. ನೀವು

ಭಾಗ್ಗಿ ಸಲು ಬಯಸದದ್ದರ ನಿಮ್ಮ ಚಿಕಿತ್ಸೆಯ ಅಂಶವೂ ಪರಿಣಾಮ ಬೋಱುವುದಿಲ್ಲ. ತನಿಖೆಯ ವೆಚ್ಚವನ್ನು ನಾನು ಭರಿಸುತ್ತೇನೆ. ಉದ್ದೇಶತ ಅಧ್ಯಯನದಲ್ಲಿಭಾಗ್ಗಿ ಸಲು ನೀವು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಒಪ್ಪಿಕ ಇಂದರ ಮಾತ್ರ ನೀವು ಸಹಿ ಮಾಡಬೋೕಕಾಗುತ್ತಿದೆ. ಈ ಡಾಕುಯಮಂಟ್ ಅನು ಓಟ್ೕ ರನ ೕಕೋಲರಂಗ ೕಲೋಜಿ ವಿಭಾಗ್ಗ್ಲಿಸುರಕ್ಷಿತ ಲಾಕರ್ನ್ಗ್ಲಿ ಸಂಗ್ರಹಿಸಲಾಗುತ್ತಿದೆ ಮತ್ತುಕಟ್ಟುನಿಟ್ಟಾದ ಗೌಪ್ಯತೆಯನ್ನು ಕಾಪಾಡಿಕ ಳುಲಾಗುತ್ತಿದೆ. ನಿಮ್ಮ ಮಾಹಿತಿಗಾಗಿ ಈ ಡಾಕುಯಮಂಟ್ಟ ನಕಲನ್ನು ನಿಮಗೆ ನೋಡಲಾಗುವುದು.

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KEY TO MASTERCHART

UHID – Unique Hospital Identification Number

APACHE II – Acute Physiology And Chronic Health Evaluation

EPASS – Estimation Of Physiologic Ability And Surgical Stress

POSSUM – Physiological And Operative Severity Score For Enumeration Of Mortality and Morbidity

GBS – Gingivobuccal sulcus

RMT – Retromolar trigone

DOI – Depth of invasion

CT – Chemotherapy

RT – Radiotherapy

M – Male

F - Female