

“A cross-sectional prospective study on the impact of pretreatment depressive symptoms on health-related quality of life in head & neck cancer patients.”

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ABSTRACT

Objective-

“A cross-sectional prospective study on the impact of pretreatment depressive symptoms on health-related quality of life in head & neck cancer patients.” (CSPS_PDS_HRQOL_HNC) is Observational (Phase-4), cross-sectional, Prospective & pilot Study which is designed to assess the prospective evaluation of the Impact of pretreatment depression symptoms & post-treatment health-related quality of life (HRQOL) and providing information that is congruent with patients’ needs is an important determinant for a patient. Satisfaction and also affect health-related quality of life (HRQOL) and anxiety and depression levels of cancer survivors. The result of this prospective study will be used to make better Design and about the conduct of future outcomes in such type of studies in this population & to improve the HRQOL of Head & Neck Cancer patients (HNC) survivors.

Research Design & Methodology-

Data of prospective pilot study of 50 patients with head and neck cancer (HNC) were collected that was carried out in the Capital urology and gastro hospital, Jaipur, JAIPUR. Values for modified BDI-II, the ratio of sex having head and neck cancer and their age along with EQ-5D was collected at the time of first follow up/visit (before treatment). Quality of life questionnaire was filled up for each subject at the start and after the completion of the study after completion of the second follow up (after treatment) so that effect of depressive symptoms on health-related quality of life (HRQOL) and their every subject can be evaluated through EQ-5D and modified BDI-II. Treatment or drug therapy was also collected from a patient diary.

Result-

In this study, out of total of 50 patients, the majority of patients were 45-65 yr. age group; and were 80% male patients and 20% female. Cancer patients were more belonged to the urban area. Most of the patients enrolled having neck cancer. Under this study 64% of male patients having neck cancer, 16% of male patients having head Cancer, and all the female patients 20% having neck cancer.

Conclusion- Overall the conclusion is that the patients having Head and neck cancer with depressive symptoms are being less depressive symptoms after counseling and the proper medication. During study, patients show good control over their depressive symptoms but no complication occurs during the study period. Patients should have 100% adherence to pharmacotherapy and what advice has been given to him. The health is on the top of a common man, so it’s very necessary to give the proper counseling with the proper medication with good assistance the medicines acts very positively, this can change the health-related quality of life in affected peoples from this type of chronic diseases. Similarly study analysis concluded that HNC Patients were fully satisfied with the treatment had been given to them by physicians at the Study site.

Keywords: **EQ-5D:** Euro Questionnaire-5 dimensions, **Modified BDI-II:** Modified back depression Inventory, **HNC:** Head and Neck Cancer, **HRQOL:** Health-Related Quality Of life, **Chemotherapy, Questionnaire.**

INTRODUCTION

Cancer basics¹

“Cancer” is a term used for diseases in which abnormal cells divide without control and are able to invade other tissues. Cancer cells can spread to other parts of the body through the blood and lymph systems. Cancer is not just one disease but many diseases. There are more than 100 different types of cancer. Most cancers are named for the organ or type of cell in which they start - for example, cancer that begins in the colon is called colon cancer; cancer that begins in melanocytes of the skin is called melanoma. Cancer is a group of more than 100 different diseases that are characterized by uncontrolled cellular growth, local tissue invasion and distant metastases.

In another words, Cancer is a generic term for a large group of diseases that can affect any part of the body. Other terms used are malignant tumours and neoplasm's. One defining feature of cancer is the rapid creation of abnormal cells that grow beyond their usual boundaries, and which can then invade adjoining parts of the body and spread to other organs. This process is referred to as metastasis. Metastases are the major cause of death from cancer.

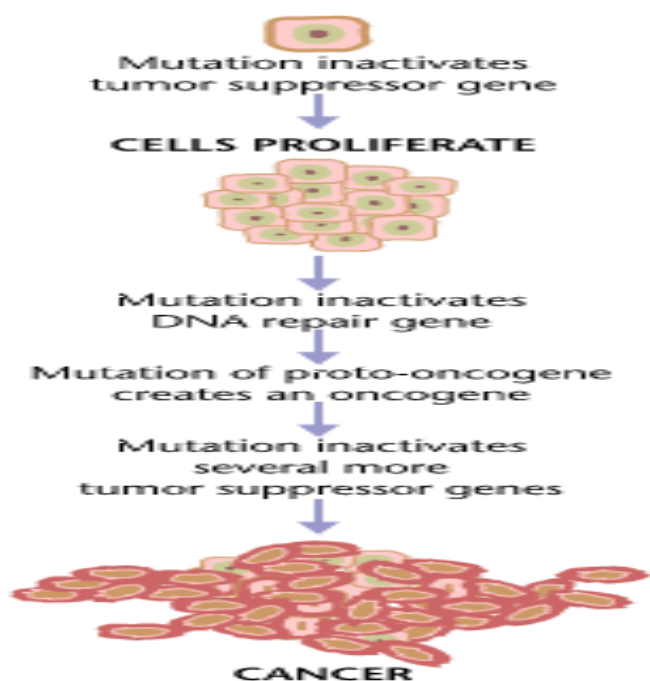


Diagram-1 Cancers are caused by a series of mutations. Each mutation alters the behaviour of the cell somewhat.¹

Types of cancer-

There are more than 100 types of cancer, including breast cancer, skin cancer, lung cancer, colon cancer, prostate cancer, and lymphoma. Symptoms vary depending on the type. Cancer treatment may include chemotherapy, radiation, and/or surgery.

Cancer types can be grouped into broader categories. The main categories of cancer include:

Carcinoma - cancer that begins in the skin or in tissues that line or cover internal organs. There are a number of subtypes of carcinoma, including adenocarcinoma, basal_cell_carcinoma, squamous_cell_carcinoma, and transitional_cell carcinoma.

Sarcoma - cancer that begins in bone, cartilage, fat, muscle, blood vessels, or other connective or supportive tissue.

Leukemia - cancer that starts in blood-forming tissue such as the bone marrow and causes large numbers of abnormal blood cells to be produced and enter the blood.

Lymphoma and myeloma - cancers that begin in the cells of the immune system.

Central nervous system cancers - cancers that begin in the tissues of the brain and spinal cord.

Origins of cancer-

All cancers begin in cells, the body's basic unit of life. To understand cancer, it's helpful to know what happens when normal cells become cancer cells.

The body is made up of many types of cells. These cells grow and divide in a controlled way to produce more cells as they are needed to keep the body healthy. When cells become old or damaged, they die and are replaced with new cells. However, sometimes this orderly process goes wrong. The genetic material (DNA) of a cell can become damaged or changed, producing mutations that affect normal cell growth and division. When this happens, cells do not die when they should and new cells form when the body does not need them. The extra cells may form a mass of tissue called a tumor.

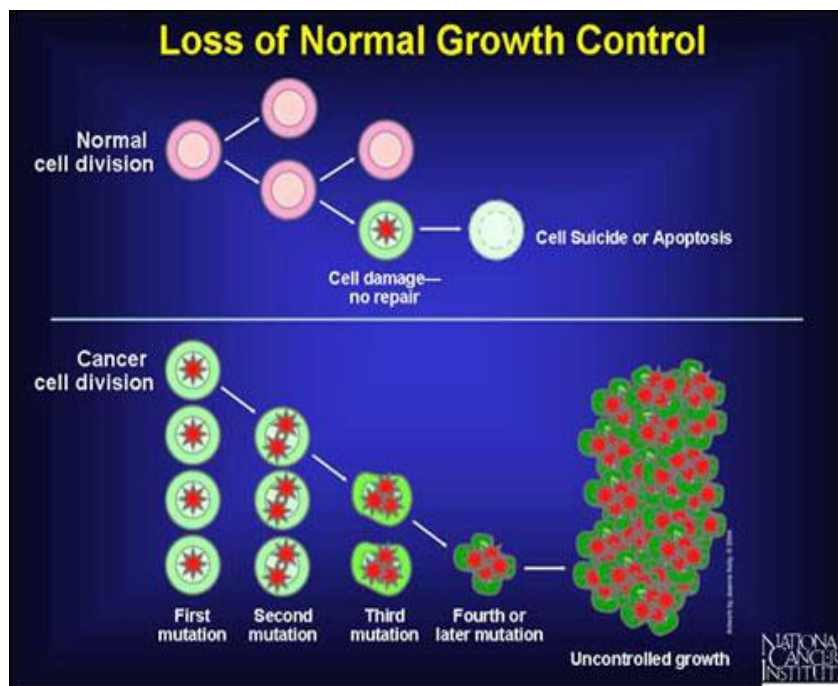


Diagram-2: loss of normal growth control.

Not all tumors are cancerous; tumors can be benign or malignant.

Benign tumors aren't cancerous. They can often be removed, and, in most cases, they do not come back. Cells in benign tumors do not spread to other parts of the body.

Malignant tumors are cancerous. Cells in these tumors can invade nearby tissues and spread to other parts of the body. The spread of cancer from one part of the body to another is called metastasis. Some cancers do not form tumors. For example, leukemia is a cancer of the bone marrow and blood.

Globalization of cancer statistics⁴

A report from the nation's leading cancer organizations shows that rates of death in the United States from all cancers for men and women continued to fall between 2001 and 2010, the most recent reporting period available.

Estimated new cases and deaths from cancer in the United States in 2014⁵:

New cases: 1,665,540 (does not include non melanoma_skin_cancers) Deaths: 585,720

An estimated 36,500 new cases of and 7900 deaths from oral cavity and pharyngeal cancers occurred in 2010 in the United States.^{2,3} Squamous cell carcinoma or a variant is the histologic type in more than 90% of these tumors. Alcohol and tobacco abuse are common etiologic factors in cancers of the oral cavity, oropharynx, and hypopharynx. Because the entire aerodigestive tract epithelium may be exposed to these carcinogens, patients with H&N cancer are at risk for developing second primary neoplasms of the H&N, lung, esophagus, and other sites that share these risk factors.

Incidence and Etiology⁶-

An estimated 36,500 new cases of and 7900 deaths from oral cavity and pharyngeal cancers occurred in 2010 in the United States. Squamous cell carcinoma or a variant is the histologic type in more than 90% of these tumors. Alcohol and tobacco abuse are common etiologic factors in cancers of the oral cavity, oropharynx, and hypopharynx. Because the entire aero digestive tract epithelium may be exposed to these carcinogens, patients with H&N cancer are at risk for developing second primary neoplasms of the H&N, lung, esophagus, and other sites that share these risk factors.

Human papilloma virus (HPV) infection is now well accepted as a risk factor for the development of squamous cancers of the oropharynx (particularly cancers of the lingual and palatine tonsils, and base of tongue). The overall incidence of HPV-positive H&N cancer is increasing in the United States, whereas the incidence of HPV-negative (primarily tobacco- and alcohol-related) cancer is decreasing.

WHO, through its cancer research agency, International Agency for Research on Cancer (IARC), maintains a classification of cancer causing agents. Ageing is another fundamental factor for the development of cancer. The incidence of cancer rises dramatically with age, most likely due to a buildup of risks for specific cancers that increase with age. The overall risk accumulation is combined with the tendency for cellular repair mechanisms to be less effective as a person grows older.

1.6 Some broad questions-

What causes cancer⁷?

Cancer arises from one single cell. The transformation from a normal cell into a tumour cell is a multistage process, typically a progression from a pre-cancerous lesion to malignant tumours. These changes are the result of the interaction between a person's genetic factors and three categories of external agents, including:

physical carcinogens, such as ultraviolet and ionizing radiation; chemical carcinogens, such as asbestos, components of tobacco smoke, aflatoxin (a food contaminant) and arsenic (a drinking water contaminant); and biological carcinogens, such as infections from certain viruses, bacteria or parasites.



Diagram-3 An invasive ductal carcinoma of the breast (pale area at the center) surrounded by spikes of whitish scar tissue and yellow fatty tissue.



Diagram-4 An invasive colorectal carcinoma (top center) in a colectomy specimen.

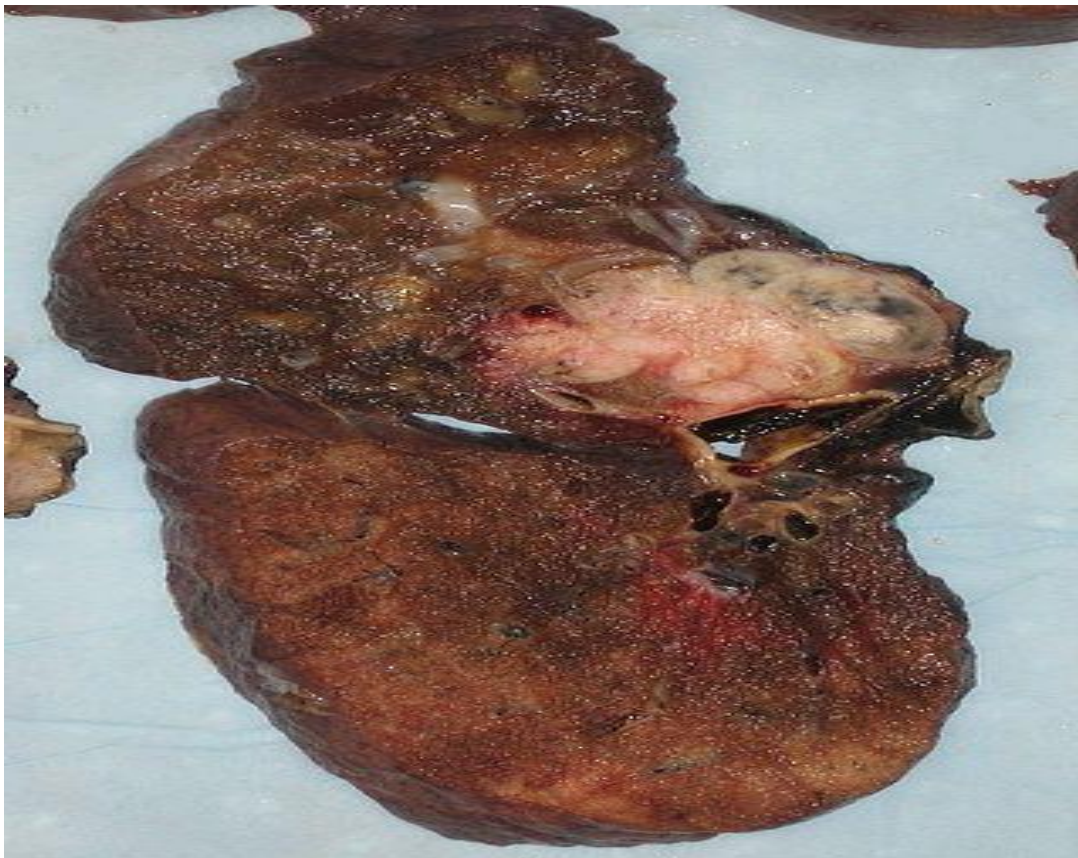


Diagram-5 A squamous-cell carcinoma (the whitish tumor) near the bronchi in a lung specimen.



Diagram-6 A large invasive ductal carcinoma in a mastectomy specimen.

Diagnosis⁹-

Most cancers are initially recognized either because of the appearance of signs or symptoms or through screening. Neither of these lead to a definitive diagnosis, which requires the examination of a tissue sample by a pathologist. People with suspected cancer are investigated with medical tests. These commonly include blood tests, X-rays, CT scans and endoscopy.

Most people are distressed to learn that they have cancer. They may become extremely anxious and depressed. The risk of suicide in people with cancer is approximately double the normal risk.

Anticancer Drugs-

Anticancer drugs are the drugs which are used in the treatment of cancer disease.

it is the chronic disease in which the whole world is affected .

Classification of Anticancer drugs-

Types	Groups	Examples	Main mechanism
Alkylating and related agents	Nitrogen mustards	Cyclophosphamide, ifosfamide, chlorambucil, melphalan, estramustine,	Intrastrand cross-linking of DNA
	Nitrosoureas	Lomustine, carmustine,	
	Platinum compounds	Carboplatin, cisplatin, oxaliplatin	
	Other	Busulfan, treosulfan, thiotepa, dacarbazine, procarbazine, temozolimide	

Antimetabolites	Folate antagonists	Methotrexate, raltitrexed, pemetrexed	Blocking the synthesis of DNA and/or RNA
	Pyrimidine pathway	Fluorouracil, capecitabine, cytarabine, gemcitabine, tegafur	
	Purine pathway	Fludarabine, cladibrine, mercaptopurine, tioguanine, pentostatin, clofarabine, nelarabine	
Cytotoxic antibiotics	Anthracyclines	Daunorubicin, doxorubicin, epirubicin, idarubicin, (mitoxantrine), (amascrine)	Multiple effects on DNA/RNA synthesis and topoisomerase action
	Other	Bleomycin, dactinomycin, mitomycin	
Plant derivatives	Taxanes Vinca alkaloids	Paclitaxel, docetaxel Vinblastine, vincristine, vindesine, vinorelbine	Microtubule assembly; prevents spindle formation
	Camptothecins Other	Irinotecan, topotecan, trabectedin, Etoposide	
Hormones/antagonists	Hormones/analogues	Diethylstilbestrol, ethinyloestradiol, medroxyprogesterone, megestrol, norhisterone, goserelin, leuporelin, triptorelin, lanreotide, octreotide	Act as physiological antagonists, antagonists or hormone synthesis inhibitors to disrupt hormone-dependent tumour growth
	Antagonists	Tamoxifen, toremifine, fulvestrant, cyproterone, flutamide, bicalutamide	
	Aromatase inhibitors	Anastrozole, letrozole, exemastine	
Protein kinase inhibitors	Tyrosine kinase inhibitors Pan kinase inhibitors	Dasatinib, erlotinib, imatinib, nilotinib, sunitinib Sorafenib	Inhibition of kinases involved in growth factor receptor transduction
Monoclonal antibodies	Anti-EGF, EGF-2	Panitumumab, trastuzumab	Blocks cell proliferation

	Anti-CD20/CD52	Rituximab, alemtuzumab	Inhibition of lymphocyte proliferation
	Anti-VEGF	Bevacizumab	Prevents angiogenesis

The main anticancer drugs can be divided into the following general categories:

Cytotoxic drugs. The mechanism of action of these drugs is discussed more fully below and summarised in Table 1; they include:

alkylating agents and related compounds, which act by forming covalent bonds with DNA and thus impeding replication

antimetabolites, which block or subvert one or more of the metabolic pathways involved in DNA synthesis

cytotoxic antibiotics, i.e. substances of microbial origin that prevent mammalian cell division

plant derivatives (vinca alkaloids, taxanes, camptothecins): most of these specifically affect microtubule function and hence the formation of the mitotic spindle.

Hormones, of which the most important are steroids (e.g. glucocorticoids, oestrogens and androgens) as well as drugs that suppress hormone secretion or antagonise hormone action.

Monoclonal antibodies: these are generally only of use in particular types of cancer.

Protein kinase inhibitors: these drugs inhibit protein (usually tyrosine) kinases that transduce growth signals in rapidly dividing cells. They have a rather restricted use.

Miscellaneous agents that do not easily fit into the above categories.

Risk factors for cancers-

Tobacco use, alcohol use, unhealthy diet and physical inactivity are the main cancer risk factors worldwide. Chronic infections from hepatitis B (HBV), hepatitis C virus (HCV) and some types of Human Papilloma Virus (HPV) are leading risk factors for cancer in low- and middle-income countries. Cervical cancer, which is caused by HPV, is a leading cause of cancer death among women in low-income countries.

The problem-

Cancer is a leading cause of death worldwide, accounting for 8.2 million deaths in 2012 (3). The most common causes of cancer death are cancers of:

Lung (1.59 million deaths)

Liver (745 000 deaths)

Stomach (723 000 deaths)

Colorectal (694 000 deaths)

Breast (521 000 deaths)

Oesophageal cancer (400 000 deaths) ⁽³⁾ .

How can the burden of cancer be reduced?

Knowledge about the causes of cancer, and interventions to prevent and manage the disease is extensive. Cancer can be reduced and controlled by implementing evidence-based strategies for cancer prevention, early detection of cancer and management of patients with cancer. Many cancers have a high chance of cure if detected early and treated adequately.

Modifying and avoiding risk factors

More than 30% of cancer deaths could be prevented by modifying or avoiding key risk factors, including:

- Tobacco use
- being overweight or obese
- unhealthy diet with low fruit and vegetable intake
- lack of physical activity
- alcohol use

- sexually transmitted HPV-infection
- urban air pollution
- indoor smoke from household use of solid fuels.

Tobacco use is the single most important risk factor for cancer causing about 22% of global cancer deaths and about 71% of global lung cancer deaths. In many low-income countries, up to 20% of cancer deaths are due to infection by HBV and HPV.

Prevention strategies

Increase avoidance of the risk factors listed above.

Vaccinate against human papilloma virus (HPV) and hepatitis B virus (HBV).

Control occupational hazards.

Reduce exposure to sunlight.

Early detection

Cancer mortality can be reduced if cases are detected and treated early. There are two components of early detection efforts:

Early diagnosis

The awareness of early signs and symptoms (for cancer types such as cervical, breast, colorectal and oral) in order to get them diagnosed and treated early before the disease becomes advanced. Early diagnosis programmes are particularly relevant in low-resource settings where the majority of patients are diagnosed in very late stages and where there is no screening.

Screening

Screening is defined as the systematic application of a test in an asymptomatic population. It aims to identify individuals with abnormalities suggestive of a specific cancer or pre-cancer and refer them promptly for diagnosis and treatment. Screening programmes are especially effective for frequent cancer types for which a cost-effective, affordable, acceptable and accessible screening test is available to the majority of the population at risk.

Examples of screening methods are: visual inspection with acetic acid (VIA) for cervical cancer in low-resource settings; PAP test for cervical cancer in middle- and high-income settings; mammography screening for breast cancer in high-income settings.

Treatment-

Cancer treatment requires a careful selection of one or more intervention, such as surgery, radiotherapy, and chemotherapy. The goal is to cure the disease or considerably prolong life while improving the patient's quality of life. Cancer diagnosis and treatment is complemented by psychological support.

Treatment of early detectable cancers

Some of the most common cancer types, such as breast cancer, cervical cancer, oral cancer and colorectal cancer have higher cure rates when detected early and treated according to best practices.

Treatment of other cancers with potential for cure

Some cancer types, even though disseminated, such as leukemias and lymphomas in children, and testicular seminoma, have high cure rates if appropriate treatment is provided.

Palliative care

Palliative care is treatment to relieve, rather than cure, symptoms caused by cancer. Palliative care can help people live more comfortably; it is an urgent humanitarian need for people worldwide with cancer and other chronic fatal diseases. It is particularly needed in places with a high proportion of patients in advanced stages where there is little chance of cure. Relief from physical, psychosocial and spiritual problems can be achieved in over 90% of advanced cancer patients through palliative care.

Palliative care strategies

Effective public health strategies, comprising of community- and home-based care are essential to provide pain relief and palliative care for patients and their families in low-resource settings.

Improved access to oral morphine is mandatory for the treatment of moderate to severe cancer pain, suffered by over 80% of cancer patients in terminal phase.

WHO response-

In 2013, WHO launched the Global Action Plan for the Prevention and Control of Non communicable Diseases 2013-2030 that aims to reduce by 25% premature mortality from cancer, cardiovascular diseases, diabetes and chronic respiratory diseases.

WHO and the International Agency for Research on Cancer (IARC), the specialized cancer

provide technical assistance for rapid, effective transfer of best practice interventions to developing countries. WHO, collaborate with other United Nations organizations and partners to: increase political commitment for cancer prevention and control; coordinate and conduct research on the causes of human cancer and the mechanisms of carcinogenesis; develop scientific strategies for cancer prevention and control; generate new knowledge, and disseminate existing knowledge to facilitate the delivery of evidence-based approaches to cancer control; develop standards and tools to guide the planning and implementation of interventions for prevention, early detection, treatment and care; facilitate broad networks of cancer control partners and experts at global, regional and national levels; strengthen health systems at national and local levels to deliver cure and care for cancer patients.

Head & neck Cancer-

Among all the types of cancer, head & neck cancer (HNC) remains a considerable challenge to both patients and health care providers. of approximately 40,000 new cases diagnosed annually, the majority present with loco regionally advanced disease (stage III or IV). The treatment of patients diagnosed with head and neck (H&N) cancer presents challenges to the surgical team. Successful outcome is assessed by traditional survival rates and by additional factors notably morbidity, functional status and quality of life (QoL). The assessment of QoL is salient when the differences in survival rates between different treatment regimens are marginal. The decision on the method to select may then be indicated by patient preference or known QoL improvements.

Now, in India, 46% patients of the total cancer patients are survived from Head and Neck Cancer (HNC).

Head and neck cancer refers to a group of biologically similar cancers that start in the lip, oral cavity (mouth), nasal cavity (inside the nose), paranasal sinuses, pharynx, and larynx. 90% of head and neck cancers are squamous cell carcinomas (HNSCC). Squamous cell carcinoma (SCC) is the most frequent malignant tumour of the head and neck region. HNSCC is the sixth leading cancer by incidence worldwide. There are 0.5 million new cases a year worldwide. Two thirds occur in industrialized nations. HNSCC usually develops in males in the 6th and 7th decade. The five-year survival rate of patients with HNSCC is about 40-50%. Originating from the mucosal lining (epithelium) of these regions. Head and neck cancers often spread to the lymph nodes of the neck, and this is often the first (and sometimes only) sign of the disease at the time of diagnosis. Head and neck cancer is strongly associated with certain environmental and lifestyle risk factors, including tobacco smoking, alcohol consumption, UV light, particular chemicals used in certain workplaces, and certain strains of viruses, such as *human papilloma virus*. These cancers are frequently aggressive in their biologic behavior; patients with these types of cancer are at a higher risk of developing another cancer in the head and neck area. Head and neck cancer is highly curable if detected early, usually with some form of surgery, but radiation therapy may also play an important role, while chemotherapy is often ineffective.

Recently, the literature on outcomes has extended to related issues including: psychological status and a discussion of what patients experience during the recovery and rehabilitation phase. This article presents a brief review of current knowledge in this expanding field for clinicians performing highly individualized treatments. The aim of this brief review is to highlight the important factors that will assist in helping to select the most beneficial treatment pathway for the patient with H&N cancer. Head and neck cancer is the sixth most common cancer worldwide.^{1,2} Ninety per cent of these cancers are squamous cell carcinomas. Men are more likely than women to succumb to the disease by a ratio of 3:1. The disparity between the sexes is becoming less pronounced in the U.K. Mortality rates are high at 54% overall.

Also, recurrence rates are high in the first year following diagnosis of the primary tumour, compared to many other cancers.

Traditional aggressive treatment, surgery followed by radiotherapy, often results in functional and psychosocial dysfunction, yet still cures only a minority of patients. Over the past three decades, investigations have explored the addition of chemotherapy, either as induction (neo adjuvant), adjuvant, or concomitant with radiation treatments.

Depression-

Diagnostic Criteria for Major Depressive Disorder and Depressive Episodes-

DSM-IV Criteria for Major Depressive Disorder (MDD)

- Depressed mood or a loss of interest or pleasure in daily activities for more than two weeks.
- Mood represents a change from the person's baseline.
- Impaired function: social, occupational, educational.
- Specific symptoms, at least 5 of these 9, present nearly every day:

Depressed mood or irritable most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad or empty) or observation made by others (e.g., appears tearful).

Decreased interest or pleasure in most activities, most of each day Significant weight change (5%) or change in appetite

Change in sleep: Insomnia or Hypersomnia.

Change in activity: Psychomotor agitation or retardation

Fatigue or loss of energy

Guilt/worthlessness: Feelings of worthlessness or excessive or inappropriate guilt

Concentration: diminished ability to think or concentrate, or more indecisiveness Suicidality: Thoughts of death or suicide, or has suicide plan

DSM – V

proposed (not yet adopted) anxiety symptoms that may indicate depression: irrational worry, preoccupation with unpleasant worries, trouble relaxing, feeling tense, fear that something awful might happen. Screen for conditions that may mimic or co exist with Major Depressive Disorder:

- Substance abuse causing depressed mood (eg. drugs, alcohol, medications)
- Medical illness causing depressed mood
- Other psychiatric disorders: mania, hypomania, bipolar, schizoaffective, schizophrenia, etc.
- Bereavement unless sex persist for > two months or show marked functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation.

MAJOR DEPRESSIVE DISORDER	ISOLATED EPISODE
Depressed Mood	Reduced self esteem and confidence
Loss of interest and enjoyment in usual activities	Ideas of guilt and unworthiness
Reduced energy and decreased activity	Pessimistic thoughts
	Disturbed sleep
	Diminished appetite
	Ideas of self harm

Table-2 Depressive Episode Criteria (may be part of Major Depressive Disorder OR an isolated episode)

The two major diagnoses for significant depressive symptoms are adjustment disorder (reactive depression) and major depression. When mental health professionals diagnose depressive syndromes, they usually use the criteria set forth in the fourth edition of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM IV). As shown in Table 1, the DSM IV defines major depression as having at least five of the following symptoms ³ 2 weeks: (1) depressed mood most of the day; (2) loss of interest or pleasure; (3) change in appetite and/or change in weight; (4) insomnia or hypersomnia; (5) psychomotor retardation or agitation; (6) loss of energy; (7) feelings of worthlessness or guilt; (8) poor concentration; and (9) thoughts of death or suicidal ideation. Referred to as the "neurovegetative symptoms" of depression, some of these symptoms are related to bodily functions.

In order to meet the criteria for major depression, one of the patient's symptoms must be either depressed mood or loss of interest/pleasure, and the individual must also be experiencing distress or impairment in social, occupational, or other important areas of functioning. Major depression is usually distinguished from an adjustment disorder by the degree, duration, or amount of symptoms.

Making the diagnosis of depression can be more complicated in cancer patients, however. Many of the neurovegetative symptoms of depression— especially loss of energy, loss of appetite, and sleep disturbance— overlap with common symptoms of cancer or other medical illnesses, and with side effects of medical treatments used in cancer patients.

Because these criteria may not be specific for depression in medical illnesses, a set of psychological criteria is often used in their place. Endicott suggested substituting the psychological symptoms of self-pity, brooding, crying spells, and pessimism for the neurovegetative symptoms.[17] Some clinicians highlight the importance of the cognitive symptoms of depression, such as depressed thoughts, hopelessness about appreciating any degree of quality in their lives, guilt or worthlessness, or persistent suicidal ideation. It is important to remember that someone who is acutely dying often becomes withdrawn and hypoactive and may exhibit neurovegetative symptoms. This is usually part of the dying process, not an episode of major depression.

Assessing Depression in Cancer Patients

Since depression is both prevalent and treatable in cancer patients, caregivers should routinely screen patients for its presence. Several predisposing factors have been correlated with the development of depression in cancer patients. These include a history of psychiatric illness, early maladjustment to cancer, poor social support, and low performance status.[18]

Assessment for depression with a rapid mental status examination is feasible and should be done in the context of a regular medical visit. Using the questions listed in, the clinician can rapidly (ie, within 5 to 10 minutes) assess the patient for depression.[19] Three areas should be assessed: (1) the patient's mood, (2) physical signs of depression (which must be evaluated clinically to determine whether fatigue, insomnia, and low libido are caused by depression or by the cancer or cancer treatment), and (3) the severity of depression.

Suicidal risk must also be assessed, as patients do not readily discuss suicidal thoughts with their caregivers. The clinician should explore how serious the thoughts are and whether the individual has personal factors (ie, prior psychiatric disorder, particularly depression or substance abuse; recent bereavement; and/or few social supports) or medical factors (i.e, poorly controlled pain, advanced stage of disease with debilitation, mild delirium with poor impulse control, and/or hopelessness or helplessness in the context of depression) that may contribute to the depression. These risk factors for suicide are summarized in.[19]

If suicidal ideation is present, a psychiatrist should be asked to evaluate the patient. If the individual appears to be at high risk, he or she should be sent to an emergency room for evaluation and possible hospitalization.

In a busy practice where this type of questioning may seem too time-consuming to ask of all patients routinely, screening tools could be given to patients in the waiting room for quick, timely assessment. Patients who report some depressive symptoms or distress on those screening instruments could be evaluated further in an interview.

Some screening tools used in oncology settings include the Hospital Anxiety and Depression Scale (HADS), Primary Care Evaluation of Mental Disorders (PRIME-MD), and the Zung Self-Rating Depression Scale.[20-22]. Memorial Sloan-Kettering Cancer Center has been using a one-item, rapid screening tool, the "distress thermometer," that has been easily completed by patients in clinic waiting rooms.[23]

One interesting study found that the one question that correlated most highly with the presence of major depression in terminally ill patients was simply, "Are you depressed?"[24] This single-item screening tool outperformed questionnaires and other screening tools for the eventual diagnostic outcome of evaluations.

1.17 Health-related quality of life (HRQOL) has become a standard end point in randomized controlled trials in oncology and may contribute to clinical decision making by presenting important information from the patient perspective.¹ Patient self-assessment of HRQOL could provide prognostic survival information beyond what is achieved by recognized factors.²⁻⁴ Measurements of HRQOL at the time of initial therapy have often been shown to be independent predictors of overall survival (OS) for patients with advanced cancer²⁻⁵ but not for those with early-stage cancer.⁶⁻⁸ The prognostic significance of changes in HRQOL scores after the initial course of treatment has also been examined with mixed results.^{2,7,9-11} Head and neck cancer (HNC) is associated with significant morbidities. Adverse effects of radiation therapy and surgery further affect HRQOL of patients with HNC. A few studies have examined the relationship between pretreatment HRQOL and survival among patients with HNC.¹²⁻¹⁷ The goal of these regimens is to improve disease control, survival, and quality of life (QOL) through the preservation of function.

Providing information that is congruent with patients' needs is an important determinant for patient Satisfaction and might also affect health-related quality of life (HRQoL) and anxiety and depression levels of cancer patients.

HRQoL is a multidimensional construct that covers the patients' perceptions of his or her physical, emotional, social, and cognitive functions. HRQoL assessment is an important aspect of cancer care. HRQoL parameters providing prognostic information can facilitate clinical decision making in terms of better treatment selection for cancer patients. Furthermore, cancer survivors often deal with adaptation problems and assessment of their HRQoL could help to improve aftercare. Cancer survivors experience high levels of psychological distress, a range of feelings and emotions that people experience in reaction to cancer including depression and anxiety, with an important impact on HRQoL. In the past decade, the role of information provision in cancer care has been acknowledged. Several studies have investigated the relationship between information provision and HRQoL, anxiety and depression, but results seem inconsistent.

1.18 Detection and treatment of HNC patients-

Primary care doctors detect most tumors on complaint of soreness in the mouth or throat by their patients. However, on enquiry GMPs preferred that this task associated with any oral symptoms should be the major remit of the dentist.⁵ A number of psychological factors explain the delay of patients with advanced H&N cancer seeking medical care. Patients who delay more than 3 months tend to be less optimistic, less committed or involved in health activities (termed 'health hardy'), cope less actively and seek less support, compared to those who seek medical attention within 3 months.⁶ The management of H&N cancer relies strongly on surgery or radiotherapy, or their combination (see Fig. 1).⁷ Surgical intervention aims to completely remove the primary cancer and any involved lymph nodes. Preservation of function is a secondary aim and finally the maintenance of aesthetics. Many H&N cancer patients are treated with high-dose radiotherapy, which as a consequence also irradiates associated sensitive tissues such as mucous membranes, nerves and circulatory structures.⁸ Increasing intensity of treatment has produced significant improvements to outcome but has raised side effects.⁸ Delay (greater than 6 weeks) in starting radiotherapy following surgery has been shown to be detrimental to 5-year local recurrence rate.⁹ Primary tumor location and disease stage are known to influence treatment selection but not co-morbidity or pre-treatment QoL.¹⁰

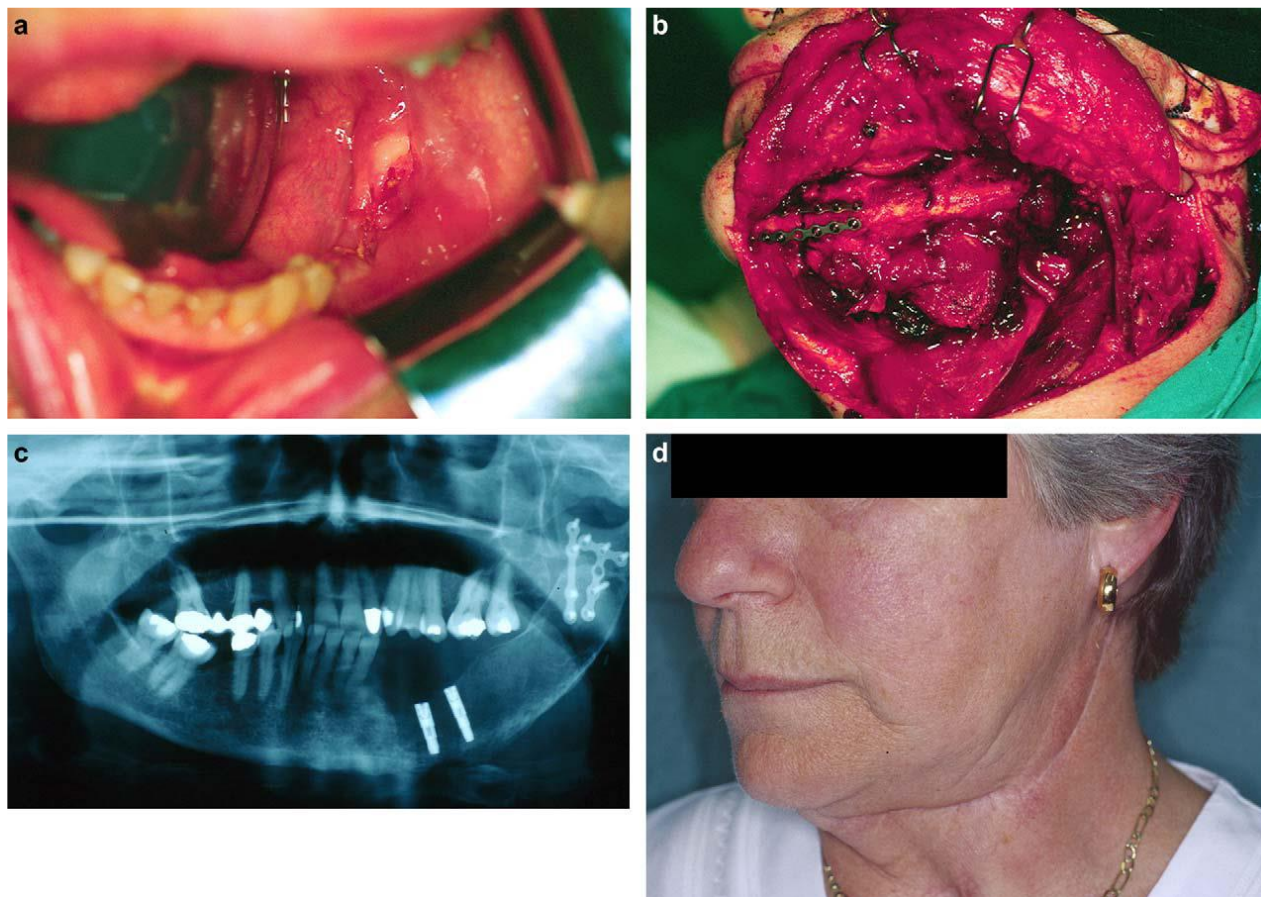


Diagram-7(a) Squamous cell carcinoma of the left posterior mandible. (b) Mandibles resection with reconstruction. (c) Postoperative pan oral radiograph showing placement of plants and implants. (d) Six months post surgery, showing good aesthetic results.

1.19 Key facts-

Cancers figure among the leading causes of death worldwide, accounting for 8.2 million deaths in 2012. Lung, liver, stomach, colorectal and breast cancers cause the most cancer deaths each year. The most frequent types of cancer differ between men and women.

About 30% of cancer deaths are due to the five leading behavioral and dietary risks: high body mass index, low fruit and vegetable intake, lack of physical activity, tobacco use, alcohol use. Tobacco use is the most important risk factor for cancer causing over 20% of global cancer deaths and about 70% of global lung cancer deaths. Cancer causing viral infections such as HBV/HCV and HPV are responsible for up to 20% of cancer deaths in low- and middle-income countries .

More than 60% of world's total new annual cases occur in Africa, Asia and Central and South America. These regions account for 70% of the world's cancer deaths. It is expected that annual cancer cases will rise from 14 million in 2012 to 22 within the next two decades.

1.20 BDI (Beck Depression Inventory)-

The **Beck Depression Inventory (BDI, BDI-1A, BDI-II)**, created by Aaron T. Beck, is a 21-question multiple-choice self-report inventory, one of the most widely used instruments for measuring the severity of depression. Its development marked a shift among health care professionals, who had until then viewed depression from a psychodynamic perspective, instead of it being rooted in the patient's own thoughts.

In its current version the questionnaire is designed for individuals aged 13 and over, and is composed of items relating to symptoms of depression such as hopelessness and irritability, cognitions such as guilt or feelings of being punished, as well as physical symptoms such as fatigue, weight loss, and lack of interest in sex.

There are three versions of the BDI—the original BDI, first published in 1961 and later revised in 1978 as the BDI-1A, and the BDI-II, published in 1996. The BDI is widely used as an assessment tool by health care professionals and researchers in a variety of settings.

The BDI was used as a model for the development of the Children's Depression Inventory (CDI), first published in 1979 by clinical psychologist Maria Kovacs.

The original BDI, first published in 1961, consisted of twenty-one questions about how the subject has been feeling. In the last week. Each question has a set of at least four possible answer choices, ranging in intensity. For example:

- (0) I do not feel sad.
- (1) I feel sad.
- (2) I am sad all the time and I can't snap out of it.
- (3) I am so sad or unhappy that I can't stand it.

When the test is scored, a value of 0 to 3 is assigned for each answer and then the total score is compared to a key to Determine the depression's severity. The standard cut-offs are as follows: *0–9: indicates minimal depression;

*10–18: indicates mild depression; *19–29: indicates moderate depression; and*30–63: indicates severe depression. Higher total scores indicate more severe depressive symptoms.

Some items on the BDI have more than one statement marked with the same score. For instance, there are two responses under the Mood heading that score a 2:

- (2a) I am blue or sad all the time and I can't snap out of it and
- (2b) I am so sad or unhappy that it is very painful.

AIM AND OBJECTIVES-

The objectives of this prospective, observational & pilot study are ---

To evaluate the impact of the pre-treatment depressive symptoms according to DSM-4 guideline on health related quality of life (HRQOL) using new approaches.To distinguish the relation between Head & Neck Cancer patients (HNC) survivors and their HRQOL.

- Treatment satisfaction.
- Impact of patient counselling on Health related quality of life (HRQOL) among Head & Neck Cancer patients.

LITERATURE SURVEY

2.1 Cancer Basics¹⁰

According to NCI (national cancer institute),updated on 03/07/2014,Cancer is a term used for diseases in which abnormal cells divide without control and are able to invade other tissues.

Cancer cells can spread to other parts of the body through the blood and lymph systems.

Cancer is not just one disease but many diseases. There are more than 100 different types of Cancer.Including breast cancer, skin cancer, lung cancer, colon cancer, prostate cancer, and lymphoma. Symptoms vary depending on the type. Cancer treatment may include chemotherapy, radiation, and/or surgery.

2.2 Globalization of Cancer¹¹

June 2011 In the JNCCN (Journal of the national comprehensive cancer network) vol.-9, no.-6

Edition a brief overview on Incidence and Etiology 36,500 new cases of and 7900 deaths from oral cavity and pharyngeal cancers occurred in 2010 in the United States. Squamous cell carcinoma or a variant is the histologic type in more than 90% of these tumors. Alcohol and tobacco abuse are common etiologic factors in cancers of the oral cavity, oropharynx, and hypopharynx. Because the entire aero digestive tract epithelium

may be exposed to these carcinogens, patients with H&N cancer are at risk for developing second primary neoplasms of the H&N, lung, esophagus, and other sites that share these risk factors.

June 2009 Meyer Francois and others in journal of clinical oncology vol.-27,

Health-related quality of life (HRQOL⁸) has become a standard end point in randomized controlled trials in oncology and may contribute to clinical decision making by presenting important information from the patient perspective.¹ Patient self-assessment of HRQOL⁸ could provide prognostic survival information beyond what is achieved by recognized factors.²⁻⁴ Measurements of HRQOL⁸ at the time of initial therapy have often been shown to be independent predictors of overall survival (OS) for patients with advanced cancer²⁻⁵ but not for those with early-stage cancer.⁶⁻⁷ The prognostic significance of changes in HRQOL⁸ scores after the initial course of treatment has also been examined with mixed results.^{2,7,9-11}

Head and neck cancer (HNC) is associated with significant morbidities. Adverse effects of radiation therapy and surgery further affect HRQOL⁸ of patients with HNC.

A few studies have examined the relationship between pretreatment HRQOL⁸ and survival among patients with HNC.¹²⁻¹⁷ In multivariate analyses, physical self-efficacy,¹² physical component summary,¹⁷ cognitive functioning,¹³ social functioning,¹³ and fatigue¹⁴ were associated with OS. Two studies assessed whether changes in HRQOL⁸ after diagnosis and treatment were related to survival.

2.3 Treatment Advancement

2006, Gerry m.humphris*,gozde ozakinei in International Journal of surgery

The management of H&N cancer relies strongly on surgery or radiotherapy, or their combination (See Fig. 1).⁷

Howren MB,Christensen AJ, Karnell LH, Funk GF Results suggest that depressive symptomatology present near the time of diagnosis can have a significant, deleterious impact on HRQOL⁸ over time in HNC survivors. Thus, it may be useful to assess depression at diagnosis to identify individuals at greater risk for poor HRQOL⁸ outcomes.

2.4 Depression And Quality Of Life

D'Antonio LL, LongSA, Zimmerman GJ, Peterman AH, Petti GH, Chonkich GD, Results demonstrate an inverse relationship between patient-reported HRQOL⁸ and depression. The lack of correlation between physician and patient ratings of HRQOL⁸ and Emotional Well-Being (EWB) stresses the importance of obtaining patient ratings in addition to traditional clinician ratings when assessing outcomes. Finally, the multidimensional construction of the FACT with its specific subscales may make it a useful clinical tool for assessing patient status and augmenting patient interviews.

Abendstein H1, Nordgren M, Boysen M, Jannert M, Silander E, Ahlner-Elmqvist M, Hammerlid E, Bjordal K. results that After the first year after treatment, recovery of the persisting side effects of treatment cannot be expected for the group as a whole. Patients must be prepared for this. Some individual patients experience improvement in global HRQL. HRQL⁸ assessments in daily clinical practice can identify patients who are in need of additional support and symptom relief.

A further report has shown that patient reported QoL is related to survival. Pre-treatment fatigue was a significant predictor of survival for patients with advanced H&N cancer.⁴⁸

O. Husson* results that Health care providers must pay more attention to patient-centered information provision. Additional research is needed to make definitive conclusions about information interventions as most results did not reach statistical significance due to methodological constraints. The quick development of the relatively young research field of patient-reported outcomes in cancer survivorship will make it possible to conduct better quality studies in the future.⁴⁹

2.5 Methods

Wikipedia of BDI (Beck Depression Inventory) accessed on 23/5/14 describes that The Beck Depression Inventory (BDI, BDI-1A, BDI-II), created by Aaron T. Beck, is a 21-question

Multiple-choice self-report inventory, one of the most widely used instruments for measuring the severity of depression. Its development marked a shift among health care professionals, who had until then viewed depression from a psychodynamic perspective, instead of it being rooted in the patient's own thoughts.

In its current version the questionnaire is designed for individuals aged 13 and over, and is composed of items relating to symptoms of depression such as hopelessness and irritability, cognitions such as guilt or feelings of being punished, as well as physical symptoms such as fatigue, weight loss, and lack of interest in sex.

There are three versions of the BDI—the original BDI, first published in 1961 and later revised in 1978 as the BDI-1A, and the BDI-II, published in 1996. The BDI is widely used as an assessment tool by health care professionals and researchers in a variety of settings.

The BDI was used as a model for the development of the Children's Depression Inventory (CDI), first published in 1979 by clinical psychologist Maria Kovacs.

2.6 Manuals of mental disorders-

BDI-II

The BDI-II was a 1996 revision of the BDI, developed in response to the American Psychiatric Association's publication of the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, which changed many of the diagnostic criteria for Major Depressive Disorder.

Items involving changes in body image, hypochondria, and difficulty working were replaced. Also, sleep loss and appetite loss items were revised to assess both increases and decreases in sleep and appetite. All but three of the items were reworded; only the items dealing with feelings of being punished, thoughts about suicide, and interest in sex remained the same. Finally, participants were asked to rate how they have been feeling for the past two weeks, as opposed to the past week as in the original BDI.

Like the BDI, the BDI-II also contains 21 questions, each answer being scored on a scale value of 0 to 3. Higher total scores indicate more severe depressive symptoms. The standardized cutoffs used differ from the original:

- 0–13: minimal depression
- 14–19: mild depression
- 20–28: moderate depression

- 29–63: severe depression.

DSM-IV

Diagnostic Criteria for Major Depressive Disorder and Depressive Episodes

DSM-IV Criteria for Major Depressive Disorder (MDD)

- Depressed mood or a loss of interest or pleasure in daily activities for more than two weeks.
- Mood represents a change from the person's baseline.
- Impaired function: social, occupational, educational.
- Specific symptoms, at least 5 of these 9, present nearly every day:
 1. **Depressed mood or irritable** most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad or empty) or observation made by others (e.g., appears tearful).
 2. **Decreased interest or pleasure** in most activities, most of each day
 3. **Significant weight change (5%) or change in appetite**
 4. **Change in sleep:** Insomnia or hypersomnia
 5. **Change in activity:** Psychomotor agitation or retardation
 6. **Fatigue or loss of energy**
 7. **Guilt/worthlessness:** Feelings of worthlessness or excessive or inappropriate guilt
 8. **Concentration:** diminished ability to think or concentrate, or more indecisiveness
 9. **Suicidality:** Thoughts of death or suicide, or has suicide plan

DSM – V proposed (not yet adopted) anxiety symptoms that may indicate depression: irrational worry, preoccupation with unpleasant worries, trouble relaxing, feeling tense, fear that something awful might happen.

Screen for conditions that may mimic or co-exist with Major Depressive Disorder:

- **Substance abuse** causing depressed mood (ex. drugs, alcohol, medications)
- **Medical illness** causing depressed mood
- **Other psychiatric disorders:** mania, hypomania, bipolar, schizoaffective, schizophrenia, etc.
- **Bereavement** unless sex persist for > two months or show marked functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation.

Depressive Episode Criteria (may be part of Major Depressive Disorder OR an isolated episode)

A	B
Depressed Mood	Reduced self esteem and confidence
Loss of interest and enjoyment in usual activities	Ideas of guilt and unworthiness
Reduced energy and decreased activity	Pessimistic thoughts
	Disturbed sleep
	Diminished appetite

Severity of Depressive Episode:

Mild: > 1 from column A plus 1-2 from column B.Or 5-6 but mild in severity and functional impairment.

Moderate: > 1 from column A plus 2-3 from column B. Or 7-8 but moderate functional impairment.

Severe: All 3 from column A plus > 3 from column B. Or fewer but any of these: severe functional impairment, psychotic case, recent suicide attempt, or has specific suicide plan or clear intent.

Plan of Research Work

Cross sectional, open label, single centric, observational, pilot, prospective study. The study will involve recruiting subjects such that a prospective analysis can be done. Values for DSM-4 and modified BDI-2 is used to examine the patient that how much the patient is affected from depression at the first and second visit and consulting will be done.

Quality of life questionnaire will be filled up for each subject at the start and after the completion of study (After completion of second follow up) so that impact of depressive symptoms of head and Neck cancer patients on Health related quality of life can be evaluated. Best treatment will be introduced as per the Indian Council of Medical Research guideline. Impact of patient counseling on Depressive symptoms & treatment or drug therapy, treatment satisfaction will be collected. Follow-up will be of 4 and 6weeks after initiation into the study. Mental disorder conditions will be recorded if present.

MATERIALS AND METHODS

3.1 Study Procedure-It consists following points:-

3.1.1 Study Design

A prospective pilot study has been carried out between April 2014 and December 2014 in Cancer clinic of the CAPITAL UROLOGY AND GASTRO HOSPITAL, Jaipur.

3.1.2 Study Population/ Research Subjects:

A total of 60 individuals that are included in this study are diagnosed with Head and Neck cancer Patients and who are matched for Inclusion criteria consecutively attending the outpatient Cancer care clinic of the Heart and General hospital, established through consultation with treating physicians are reviewed. They are over 25 years of age and underwent treatment with various therapies. This study is approved by the scientific and Institutional Ethic Committee (IEC) of the CAPITAL UROLOGY AND GASTRO HOSPITAL, Jaipur. All study subjects gave written and oral informed consent as they were recruited at the Cancer clinic. Subjects are randomly selected in this study who meets the Inclusion criteria. Patients with Exclusion criteria as per study protocol are not included in this study.

3.1.3 Patient Enrolment:

Those patients, who met the inclusion criteria, are enrolled into the study after their informed consent was obtained. Patient demographics like age, sex, weight, family history, mood were recorded in The CRF. The study patients' medical histories were reviewed with particular attention to previous consult from doctor.

Diagnosis of various depressive symptoms was based on assessment of the respective symptom. Modified BDI-II Calculations was calculated in all subjects.

Depression was defined when at-least 5 depressive symptoms are present in the head and neck cancer Patients HNC out of 9 symptoms. Patients were considered as smokers if they were active smokers or if they had discontinued smoking during the previous year. Thus past and present medical and medication history is mentioned in (CRF) and QOL were filled up for each subject before treatment to establish baseline. All the Patients in this pilot study received counselling.

3.1.4 Patient Counselling And Follow Up

The all patients will be counselled regarding disease, medication, exercise, care, personal hygiene, self monitoring of mood and Behaviour. The patients will be asked to come back for follow-up once a month, for a period of 30 days. During each follow-up, the patients will be educated, regarding their disease, medication and life style modification.

Initially, base line of BDI-II was noted for all 60 patients. Second intervention will be followed by quality of life measurement by using modified BDI-II questionnaire and treatment Satisfaction.

3.1.5 Study Variables

The dependent variable was the quality of life score, the independent variables were the Treatment, Behaviour, Age, gender, educational level, marital status, hypertension, Cancer duration were used as control variables.

The Health Related Quality of Life (HRQL) scale was defined as the Individuals perception of their situation in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns. This is a broad concept affected in a complex way by the individual's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment.

It is known that in order to achieve satisfactory adherence patients must possess adequate knowledge about self-care behaviour and that attitudes play an important role in changing adherence behaviour, since they predict and explain human behaviour.

3.1.6 Data Collection:

After getting informed consent, patients were invited to participate when they had an appointment with their physician, and then interviewed in order to complete a CRF regarding certain personal characteristics, as well as to register the medical prescription (Various therapies). One month later, the patients again visited to measure treatment of depressive symptoms and to ask about their quality of life with the help of Modified BDI-II.

3.2 Material of Study

APPENDIX I : INFORMED CONSENT FORM

APPENDIX II : STUDY PROTOCOL SYNOPSIS

APPENDIX III : STUDY PROTOCOL

APPENDIX IV : CASE REPORT FORM (CRF)

APPENDIX V : Modified BDI-II QUALITY OF LIFE QUESTIONNAIRE, DSM-IV And EQ-5D .

4. Results

4.1 Study Population

A prospective pilot study was carried out by enrolling 50 patients of Head and Neck cancer in CAPITAL UROLOGY AND GASTRO HOSPITAL, Jaipur

A baseline data of HNC patients (n=50) were recorded initially and were followed up for improvement in depression and their HRQOL. Patients received counseling at each follow up.

4.2 Baseline Demographic Detail Of Patients.

4.2.1- Out of total enrolled 50 patients, 12 with age \leq 50 year and 38 with age $>$ 50 year were found, represented in (table 4.1)

AGE GROUP	FREQUENCY	PERCENTAGE
\leq 50 YEAR	12	24%
$>$ 50 YEAR	38	76%
TOTAL	50	100%

Table 4.1 Age details of HNC Patients.

4.2.2 Sex

Out of total 50 study patients, 40 Males (80%) and 10 females (20%) were enrolled under study, represented in (table 4.2)

Table 4.2 Sex details of HNC Patients.

SEX	FREQUENCY	PERCENTAGE
MALE	40	80%
FEMALE	10	20%
TOTAL	50	100%

4.2.3 Patient Details affected from Head and Neck Cancer.

RATIO	HEAD CANCER	NECK CANCER	TOTAL
MALE	8	32	40
MALE %	16%	64%	80%
FEMALE	0	10	10
FEMALE %	0%	20%	20%

4.3 Descriptive statistical details for baselines and follow up variables of the questionnaire of modified back depression inventory-II.

4.3.1 Sadness

Quality of life accessed before and after therapy by modified BDI-II Questionnaire contained 21 dimensions, each with four levels i.e. 0 for no problem, 1 for some problem, 2 for much problem, 3 for severe problem that they can't tolerate the Condition and it is the worst condition.

SADNESS		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	20	13	12	9	8	-
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	4	2	4	2	2	-
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	50%	32.5%	30%	22.5%	20%	--
	FEMALE%	-	-	40%	20%	40%	20%	20%	-

Table-4.3.1 (a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_SADNESS		ATQOL_SADNESS	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	--	--	--	--
1	24	48%	15	30%
2	16	32%	11	22%
3	10	20%	---	---
TOTAL	50	100.0%	26	100.0%
MISSING	--	--	24	---
TOTAL %	--	--	50	---

Table-4.3.1(b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 40 male patients, there was no response on point-0 at both conditions before treatment and after treatment. Out of Total 50 patients, no patients, 24 Patient (48%), 16 patients (32%), 10 patients (20%) respond for level 0, 1, 2 and 3 respectively for Sadness before therapy and counseling. likely out of total 26 patients, no patients, 15 patients (30%), 11 patients (22%), no patients responded for level 0, 1, 2 and 3 respectively for QOL_ Sadness at the end of the study. About 24 patients failed to respond for QOL. Frequencies for each level with valid percent are shown in table 4.3.1(b).

4.3.2-PESSIMISM-

PESSIMISM	LEVELS	BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	18	13	14	10	8	2
TOTAL	40	40	40	40	40	40	40	40	
FEMALE	-	-	3	1	3	1	4	-	
TOTAL	10	10	10	10	10	10	10	10	
MALE%	-	-	45%	32.5%	35%	25%	20%	5%	
FEMALE%	-	-	30%	10%	30%	10%	40%	-	

Table - 4.3.2 (a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ PESSIMISM		ATQOL_ PESSIMISM	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	21	42	14	28
2	17	34	11	22
3	12	24	2	4
TOTAL	50	100	27	54
MISSING	-	-	23	46
TOTAL %	50	100	50	100

Table - 4.3.2 (b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 21 Patient (42%), 17 patients (34%), 12 patients (24%) respond for level 0, 1, 2 and 3 respectively for pessimism before therapy and counseling. likely out of total 27 patients, no patients, 14 patients (28%), 11 patients (22%), 2 patients (4%) responded for level 0, 1, 2 and 3 respectively for QOL_ Pessimism at the end of the study.

4.3.3 PAST FAILURE-

Past failure		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	16	11	16	8	8	3
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	4	1	3	2	3	1
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	40	27.5	40	20	20	7.5
	FEMALE%	-	-	40	10	30	20	30	10

Table - 4.3.3(a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ PAST FAILURE		ATQOL_ PAST FAILURE	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	20	40	12	24
2	19	38	11	22
3	11	22	4	8
TOTAL	50	100	27	54
MISSING	-	-	23	46
TOTAL %	50	100	50	100

Table-4.3.3 (b) showing frequencies and valid percentage at various levels at before and after therapy and counseling

Out of Total 50 patients, no patients, 20 Patient (40%), 19 patients (38%), 11 patients (22%) respond for level 0, 1, 2 and 3 respectively for Past Failure before therapy and counseling. likely out of total 27 patients, no patients, 12 patients (24%), 11 patients (22%), 4 patients (8%) responded for level 0, 1, 2 and 3 respectively for QOL_ Past failure at the end of the study.

4.3.4-LOSS OF PLEASURE-

Loss of pleasure		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	8	6	18	12	14	4
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	2	1	6	2	2	1
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	20	15	45	30	35	10
	FEMALE%	-	-	20	10	60	20	20	10

Table-4.3.4 (a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ LOSS OF PLEASURE		ATQOL_ LOSS OF PLEASURE	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	10	20	7	14
2	24	48	14	28
3	16	32	5	10
TOTAL	50	100	26	52
MISSING	-	-	24	48
TOTAL %	50	100	50	100

Table-4.3.4 (b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 10 Patient (20%), 24 patients (48%), 16 patients (32%) respond for level 0, 1, 2 and 3 respectively for loss of pleasure before therapy and counseling. likely out of total 26 patients, no patients, 7 patients (14%), 14 patients (28%) and 5 patients (10%) responded for level 0, 1, 2 and 3 respectively for QOL_ loss of pleasure at the end of the study.

4.3.5- GUILTY FEELING-

Guilty feeling		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	16	6	16	4	8	4
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	1	-	3	1	6	1
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	40	15	40	10	20	10
	FEMALE%	-	-	10	-	30	10	60	10

Table-4.3.5(a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ Guilty feeling		ATQOL_ Guilty feeling	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	17	34	6	12
2	19	38	5	10
3	14	28	5	10
TOTAL	50	100	16	32
MISSING	-	-	34	68
TOTAL %	50	100	50	100

Table 4.3.5 (b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 17 Patient (34%), 19 patients (38%), 14 patients (28%) respond for level 0, 1, 2 and 3 respectively for guilty feeling before therapy and counseling. likely out of total 16 patients, no patients, 6 patients (12%), 5 patients (10%) and 5 patients (10%) responded for level 0, 1, 2 and 3 respectively for QOL_ Guilty feeling at the end of the study

4.3.6 -PUNISHMENT FEELINGS-

Punishment feeling		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	8	-	16	2	16	4
TOTAL	40	40	40	40	40	40	40	40	
FEMALE	-	-	2	-	2	-	6	1	
TOTAL	10	10	10	10	10	10	10	10	
MALE%	-	-	20	-	40	5	40	10	
FEMALE%	-	-	20	-	20	-	60	-	

Table-4.3.6 (a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ Punishment feeling		ATQOL_ Punishment feeling	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	10	20	-	-
2	18	36	2	4
3	22	44	5	10
TOTAL	50	100	7	14
MISSING	-	-	43	86
TOTAL %	50	100	50	100

Table 4.3.6 (b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 10 Patient (20%), 18 patients (36%), 22 patients (44%) respond for level 0, 1, 2 and 3 respectively for punishment feeling before therapy and counseling. likely out of total 7 patients, no patients, no patients, 2 patients (4%), 5 patients (10%) responded for level 0, 1, 2 and 3 respectively for QOL_ Punishment feeling at the end of the study.

4.3.7-SELF-DISLIKE

SELF DISLIKE		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	14	1	18	4	8	1
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	2	-	2	-	6	1
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	35	25	45	10	20	2.5
	FEMALE%	-	-	2	-	20	-	60	10

Table- 4.3.7(a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ SELF-DISLIKE		ATQOL_ SELF-DISLIKE	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	16	32	1	2
2	20	40	4	8
3	14	28	2	4
TOTAL	50	100	7	14
MISSING	-	-	43	86
TOTAL %	50	100	50	100

Table-4.3.7 (b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 16 Patient (32%), 20 patients (40%), 14 patients (28%) respond for level 0, 1, 2 and 3 respectively for self-dislike before therapy and counseling. likely out of total 7 patients, no patients, 1 patient (2%), 4 patients (8%), 2 patients (4%) responded for level 0, 1, 2 and 3 respectively for QOL_ Self-dislike at the end of the study.

4.3.8- Self criticalness

Self criticalness		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	16	-	16	1	8	1
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	3	-	3	-	4	1
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	40	-	40	2.5	45	2.5
	FEMALE%	-	-	30	-	30	-	40	10

Table-4.3.8 (a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ Self criticalness		ATQOL_ Self criticalness	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	19	38	-	-
2	19	38	1	2
3	12	24	2	4
TOTAL	50	100	3	6
MISSING	-	-	47	94
TOTAL %	50	100	50	100

Table-4.3.8 (b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 19 Patient (38%), 19 patients (38%), 12 patients (24%) respond for level 0, 1, 2 and 3 respectively for Self criticalness before therapy and counseling. likely out of total 3 patients, no patients, no patients, 1 patient (2%) and 2 patient (4%), responded for level 0, 1, 2 and 3 respectively for QOL_ Self criticalness at the end of the study.

4.3.9 SUICIDAL THOUGHTS-

Suicidal thoughts/ wishes		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	14	-	16	2	10	-
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	3	-	4	-	3	1
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	35	-	40	5	25	-
	FEMALE%	-	-	30	-	40	-	30	10

Table 4.3.9(a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ Suicidal thoughts/ wishes		ATQOL_ Suicidal thoughts/ wishes	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	17	34	-	-
2	20	40	2	4
3	13	26	1	2
TOTAL	50	100	3	6
MISSING	-	-	47	94
TOTAL %	50	100	50	100

Table 4.3.9(b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 17 Patient (34%), 20 patients (40%), 13 patients (26%) respond for level 0, 1, 2 and 3 respectively for Suicidal thoughts/ wishes before therapy and counseling. likely out of total 3 patients, no patients, no patients, 2 patients (4%), and 1 patients (2%) responded for level 0, 1, 2 and 3 respectively for QOL_ Suicidal thoughts/ wishes at the end of the study.

4.4.0 CRYING

Crying		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	10	-	16	2	14	4
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	2	-	4	1	4	1
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	25	-	40	5	35	10
	FEMALE%	-	-	20	-	40	10	40	10

Table - 4.4.0(a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ CRYING		ATQOL_ CRYING	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	12	24	-	-
2	20	40	3	6
3	18	36	5	10
TOTAL	50	100	8	16
MISSING	-	-	42	84
TOTAL %	50	100	50	100

Table 4.4.0(b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 12Patient (24%), 20patients (40%), 18patients (36%) respond for level 0, 1, 2and 3 respectively for Crying before therapy and counseling. likely out of total 8 patients, no patients, no patients , 3 patients (6%), and 5 patients (10%) responded for level 0, 1, 2 and 3 respectively for QOL crying at the end of the study.

4.4.1 AGITATION

Agitation		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	18	2	18	3	4	1
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	2	-	4	1	4	-
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	45	5	45	7.5	10	2.5
	FEMALE%	-	-	20	-	40	40	40	-

Table 4.4.1(a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ AGITATION		ATQOL_ AGITATION	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	20	40	2	4
2	22	44	4	8
3	8	16	1	2
TOTAL	50	100	7	14
MISSING	-	-	45	86
TOTAL %	50	100	50	100

Table 4.4.1(b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 20 Patient (40%), 22 patients (44%), 8 patients (16 %) respond for level 0, 1, 2 and 3 respectively for agitation before therapy and counseling. likely out of total 7 patients, no patients, 2 patients (4%), 4 patients (8%), And 1 patients (2%) responded for level 0, 1, 2 and 3 respectively for QOL_ Agitation at the end of the study.

4.4.2 LOSS OF INTEREST

Loss of interest		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	12	2	18	3	10	7
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	4	-	2	-	2	1
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	30	5	45	7.5	25	17.5
	FEMALE%	-	-	40	-	20	-	20	10

Table 4.4.2(a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ LOSS OF INTEREST		ATQOL_ LOSS OF INTEREST	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	16	32	2	4
2	20	40	3	6
3	12	24	8	16
TOTAL	50	100	13	26
MISSING	-	-	37	74
TOTAL %	50	100	50	100

Table 4.4.2(b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 16 Patient (32%), 20 patients (40%), 12 patients (24%) respond for level 0, 1, 2 and 3 respectively for loss of interest before therapy and counseling. likely out of total 13 patients, no patients, 2 patients (4%), 3 patients (6%), and 8 patients (16%) responded for level 0, 1, 2 and 3 respectively for QOL_ loss of interest at the end of the study.

4.4.3 INDECISIVENESS

indecisiveness		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	10	-	12	2	18	4
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	2	-	4	1	4	1
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	25	-	30	5	45	10
	FEMALE%	-	-	20	-	40	10	40	10

Table 4.4.3(a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ INDECISIVENESS		ATQOL_ INDECISIVENESS	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	12	24	-	-
2	16	32	3	6
3	22	44	5	10
TOTAL	50	100	8	16
MISSING	-	-	42	84
TOTAL %	50	100	50	100

Table 4.4.3(b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 12 Patient (24%), 16 patients (32%), 22 patients (44%) respond for level 0, 1, 2 and 3 respectively for indecisiveness before therapy and counseling. likely out of total 8 patients, no patients, no patients, 3 patients (6%), 5 patients (10%) responded for level 0, 1, 2 and 3 respectively for QOL_ indecisiveness at the end of the study.

4.4.4 WORTHLESSNESS

worthlessness		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	8	-	16	2	16	3
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	2	-	4	1	4	-
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	20	-	40	5	40	7.5
	FEMALE%	-	-	20	-	40	10	40	-

Table 4.4.4(a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ WORTHLESSNESS		ATQOL_ WORTHLESSNESS	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	10	20	-	-
2	20	40	3	6
3	20	40	3	6
TOTAL	50	100	6	12
MISSING	-	-	44	88
TOTAL %	50	100	50	100

Table 4.4.4(b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 10 Patient (20%), 20 patients (40%), 20 patients (40%) respond for level 0, 1, 2 and 3 respectively for Worthlessness before therapy and counseling. likely out of total 6 patients, no patients, no patients, 3 patients (6%), 3 patients (6%) responded for level 0, 1, 2 and 3 respectively for QOL_ Worthlessness the end of the study.

4.4.5 LOSS OF ENERGY

Loss of energy		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	8	-	16	3	16	4
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	2	-	4	-	4	-
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	20	-	40	7.5	40	10
	FEMALE%	-	-	20	-	40	-	40	-

Table 4.4.5 (a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ LOSS OF ENERGY		ATQOL_ LOSS OF ENERGY	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	10	20	-	-
2	20	40	3	6
3	20	40	4	8
TOTAL	50	100	7	14
MISSING	-	-	43	86
TOTAL %	50	100	50	100

Table 4.4.5(b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 10 Patient (20%), 20 patients (40%), 20 patients (40%) respond for level 0, 1, 2 and 3 respectively for loss of energy before therapy and counseling. likely out of total 7 patients, no patients, no patients, 3 patients (6%), and 4 patients (8%) responded for level 0, 1, 2 and 3 respectively for QOL_ loss of energy at the end of the study.

4.4.6 CHANGES IN SLEEPING PATTERN

Changes in sleeping pattern		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	4	-	16	2	20	7
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	4	-	4	-	2	1
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	10	-	40	5	50	17.5
	FEMALE%	-	-	40	-	40	-	20	10

Table 4.4.6(a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ CHANGES IN SLEEPING PATTERN		ATQOL_ CHANGES IN SLEEPING PATTERN	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	8	16	-	-
2	20	40	2	4
3	22	44	8	16
TOTAL	50	100	10	20
MISSING	-	-	40	80
TOTAL %	50	100	50	100

Table 4.4.6(b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 8 Patient (16%), 20 patients (40%), 22 patients (44%) respond for level 0, 1, 2 and 3 respectively for change in sleeping pattern before therapy and counseling. likely out of total 10 patients, no patients, no patients, 2 patients (4%), 8 patients (16%) responded for level 0, 1, 2 and 3 respectively for QOL_ changes in sleeping pattern at the end of the study.

4.4.7 IRRATIBILITY

Irritability		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	18	-	18	5	4	1
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	3	-	3	-	4	1
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	45	-	45	12.5	10	2.5
	FEMALE%	-	-	30	-	30	-	40	10

Table 4.4.7(a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ IRRATIBILITY		ATQOL_ IRRATIBILITY	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	21	42	-	-
2	21	42	5	10
3	8	16	2	4
TOTAL	50	100	10	20
MISSING	-	-	40	80
TOTAL %	50	100	50	100

Table 4.4.7(b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 21 Patient (42%), 21 patients (42%), 8 patients (16%) respond for level 0, 1, 2 and 3 respectively for Irritability before therapy and counseling. likely out of total 10 patients, no patients, no patients, 5 patients (10%), and 2 patients (4%) responded for level 0, 1, 2 and 3 respectively for QOL_ irritability at the end of the study.

4.4.8 CHANGES IN APPETITE

Changes in appetite		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	4	-	18	1	18	5
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	2	-	3	-	5	2
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	10	-	45	2.5	45	12.5
	FEMALE%	-	-	20	-	30	-	50	20

Table 4.4.8(a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ CHANGES IN APPETITE		ATQOL_ CHANGES IN APPETITE	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	6	12	-	-
2	21	42	1	2
3	23	46	7	14
TOTAL	50	100	8	16
MISSING	-	-	42	84
TOTAL %	50	100	50	100

Table 4.4.8(b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 6 Patient (12%), 21 patients (42%), 23 patients (46%) respond for level 0, 1, 2 and 3 respectively for changes in appetite before therapy and counseling. likely out of total 8 patients, no patients, no patients, 1 patients (2%), and 7 patients (14%) responded for level 0, 1, 2 and 3 respectively for QOL_ changes in appetite at the end of the study.

4.4.9 CONCENTRATION DIFFICULTY

Conc. Difficulty		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	4	-	16	2	20	3
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	2	-	4	-	4	1
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	10	-	40	5	50	7.5
	FEMALE%	-	-	20	-	40	-	40	10

Table-4.4.9(a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ CONCENTRATION DIFFICULTY		ATQOL_ CONCENTRATION DIFFICULTY	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	6	12	-	-
2	20	40	2	4
3	24	48	4	8
TOTAL	50	100	6	12
MISSING	-	-	44	88
TOTAL %	50	100	50	100

Table 4.4.9 (b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 6 Patient (12%), 20 patients (40%), 24 patients (48%) respond for level 0, 1, 2 and 3 respectively for concentration difficulty before therapy and counseling. likely out of total 6 patients, no patients, no patients, 2 patients (4%), and 4 patients (8%) responded for level 0, 1, 2 and 3 respectively for QOL_ concentration difficulty at the end of the study.

4.5.0 - TIREDNESS/FATIGUE-

Tiredness or fatigue		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	4	-	20	4	16	2
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	2	-	4	-	4	1
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	10	-	50	10	40	5
	FEMALE%	-	-	20	-	40	-	40	10

Table- 4.5.0 (a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ TIREDNESS/FATIGUE		ATQOL_ TIREDNESS/FATIGUE	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	6	12	-	-
2	24	48	4	8
3	20	40	3	6
TOTAL	50	100	7	14
MISSING	-	-	43	86
TOTAL %	50	100	50	100

Table-4.5.0 (b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 24 Patient (48%), 16 patients (32%), 10 patients (20%) respond for level 0, 1, 2 and 3 respectively for Tiredness or fatigue before therapy and counseling. likely out of total 7 patients, no patients, no patients, 4 patients (8%), 3 patients (6%) responded for level 0, 1, 2 and 3 respectively for QOL_ Tiredness or fatigue at the end of the study.

4.5.1- Loss Of Interest Of Sex-

Loss of interest in sex		BT-0	AT-0	BT-1	AT-1	BT-2	AT-2	BT-3	AT-3
	MALE	-	-	10	-	18	4	12	3
	TOTAL	40	40	40	40	40	40	40	40
	FEMALE	-	-	3	-	3	-	4	1
	TOTAL	10	10	10	10	10	10	10	10
	MALE%	-	-	25	-	45	10	30	7.5
	FEMALE%	-	-	30	-	30	-	40	10

Table-4.5.1 (a) showing the frequencies and percentage in various levels in male and females separately.

LEVELS	BTQOL_ LOSS OF INTEREST OF SEX		ATQOL_ LOSS OF INTEREST OF SEX	
	FREQUENCY	VALID PERCENTAGE	FREQUENCY	VALID PERCENTAGE
0	-	-	-	-
1	13	26	-	-
2	21	42	4	8
3	16	32	4	8
TOTAL	50	100	8	16
MISSING	-	-	42	84
TOTAL %	50	100	50	100

Table-4.5.1 (b) showing frequencies and valid percentage at various levels at before and after therapy and counseling.

Out of Total 50 patients, no patients, 13Patient (26%), 21 patients (42%), 16 patients (32%) respond for level 0, 1, 2 and 3 respectively for Loss of interest in sex before therapy and counseling. likely out of total 8 patients, no patients, no patients, 4 patients (8%), 4 patients (8%) responded for level 0, 1, 2 and 3 respectively for QOL_ Loss of interest in sex at the end of the study.

4.5.2 EQ-5D

“EUROPIAN QUESTIONNAIRE-5 DIMENSIONAL”

It is the Questionnaire which have 5 dimensions; like -

MOBILITY

SELF CARE

USUAL ACTIVITIES

PAIN/ DISCOMFORT

ANXIETY/ DEPRESSION

And these all have 3 levels 0,1 and 2; In which-

- 0- having no problem
- 1- having some problems
- 2- having much problem.

Stage	Before Treatment															After Treatment																	
Que	Mobility			Selfcare			Usual Act.			Pain discomfort			Anxiety / Depression			Mobility			Selfcare			Usual Act.			Pain discomfort			Anxiety / Depression					
Points	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2
Male	12	8	20	11	9	20	12	6	22	10	8	22	2	18	20	20	12	8	21	13	6	20	16	4	28	10	2	6	24	10			
Female	3	1	6	1	8	1	0	2	8	0	3	7	0	2	8	4	6	0	2	8	0	2	8	0	3	7	0	2	8	0			
TOTAL	15	9	26	12	17	21	12	8	30	10	11	29	2	20	28	24	18	8	23	21	6	22	24	4	31	17	2	8	32	10			

		BEFORE TREATMENT	AFTER TREATMENT
MOBILITY	0	15	24
	1	9	18
	2	26	8
SELF CARE	0	12	23
	1	17	21
	2	21	6
USUAL-ACTIVITIES	0	12	22
	1	8	24
	2	30	4
PAIN/DISCOMFORT	0	10	31
	1	11	17
	2	29	2
ANXIETY	0	2	8
	1	20	32
	2	28	10

MOBILITY

In the before treatment 15 patients responded-0,

9 patients responded-1

26 patients responded-2

While after treatment,

24 patients responded-0

18 patients responded-1

8 patients responded- 2

Self care

In the before treatment 12 patients responded-0,

7 patients responded-1

21 patients responded-2

While after treatment,

23 patients responded-0

21 patients responded-1

6 patients responded- 2

Usual activities

In the before treatment 12 patients responded-0,

8 patients responded-1

30 patients responded-2

While after treatment,

22 patients responded-0

24 patients responded-1

4 patients responded- 2

Pain/discomfort

In the before treatment 10 patients responded-0,

11 patients responded-1

29 patients responded-2

While after treatment,

31 patients responded-0

17 patients responded-1

2 patients responded- 2

Anxiety/depression

In the before treatment 2 patients responded-0,

20 patients responded-1

28 patients responded-2

While after treatment,

8 patients responded-0

32 patients responded-1

10 patients responded- 2

Conclusion

This prospective, pilot, observational study performed confirmed the hypothesis that systemic identification administered through continued physician follow-up and patients counseling will improve adherence to therapy and therefore improvement in treatment effectiveness in head and neck cancer patients. Study conclusion shows lack of proper knowledge about disease and patient counseling and chronic treatment, most of patients having disease and its treatment lightly and shows lower adherence attitude from study analysis concluded that females are generally more aware than males for adherence. There was significant reduction in their ATQOL and BTQOL values in different comparison groups after each level of follow up. Study conclusion shows that most HNC patients recorded with depression. Statistical analysis concluded that 64% male patients affected from neck cancer while 20% females are affected from neck cancer. Overall the conclusion is that the patients having Head and neck cancer with depressive symptoms are being less depressive symptoms after counseling and the proper medication. During study patients shows good control over their depressive symptoms but no complication occur during study period. Patients should have 100% adherence to pharmacotherapy and what advice has been given to him. The health is on the top of a common man, so it's very necessary to give the proper counseling with the proper medication with good assistance the medicines acts very positively, this can change the health related quality of life in affected peoples from this type of chronic diseases. Similarly study analysis concluded that HNC Patients were fully satisfied with the treatment had been given to them by physicians at Study site.

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