NUTRITIONAL ASSESSMENT AND INTERVENTION IN LUNG CANCER PATIENTS UNDERGOING TREATMENT

INSTITUTION

DEPARTMENT OF MEDICAL ONCOLOGY

MADRAS MEDICAL COLLEGE

&

RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL

CHENNAI-600 003

Dissertation submitted to

THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY

in partial fulfillment of the requirements

for the award of the degree of

D.M (MEDICAL ONCOLOGY) - BRANCH-VII

AUGUST 2013

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DECLARATION

I solemnly declare that this dissertation titled "**Nutritional assessment and intervention in lung cancer patients undergoing treatment**" is done by me in the Department of Medical Oncology, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai under the guidance and supervision of Prof. K.KALAICHELVI, MD., DM., Professor & Head of the Department, Department of Medical Oncology, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai. This dissertation is submitted to the Tamil Nadu Dr. MGR Medical University, Chennai in partial fulfillment of the university requirements for the award of the degree of DM (Medical Oncology).

Place: Chennai **Dr. P.N.SATHIYAMOORTHY**.

Date :

CERTIFICATE

This is to certify that the Dissertation entitled, "**Nutritional assessment and intervention in lung cancer patients undergoing treatment**" is the bonafide record work done by, **Dr. P.N.SATHIYAMOORTHY** under our guidance and supervision in the Department of Medical Oncology, Rajiv Gandhi Government General Hospital, Madras Medical College, Chennai, submitted as partial fulfillment for the requirements of D.M. Degree examination Branch VII MEDICAL ONCOLOGY, AUGUST 2013, under The Tamilnadu Dr. M.G.R. Medical University, Chennai.

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CONTENTS

ABBREVIATIONS

BEE - BASAL ENERGY EXPENDITURE

BIA - BIOELECTRIC IMPEDANCE ANALYSIS

BMI - BODY MASS INDEX

CRP- C-REACTIVE PROTEIN

DC- DIETARY COUNSELING

ECOG SCORE- EASTERN COOPERATIVE ONCOLOGY GROUP

EORTC- EUROPIAN ORGANISATION FOR RESEARCH AND TREATMENT OF CANCER

EPA – EICOSOPENTOIC ACID

FACT-L FUNCTIONAL ASSESSMENT OF CANCER THERAPY

GIT- GASTROINTESTINAL TRACT

HT- HEIGHT

IBW - IDEAL BODY WEIGHT

IL – INTERLEUKIN

LBM- LEAN BODY MASS

LCSS- . LUNG CANCER SYMPTOM SCALE

LMF- LIPID MOBILIZING FACTOR

MAC- MID ARM CIRCUMFERENCE

MAMC - MID ARM MUSCLE CIRCUMFERENCE

MNT- MINI NUTRITIONAL ASSESSMENT TOOL

N3 PUFA- N-3 POLYUNSATURATED FATTY ACIDS

OS- ORAL SUPPLEMENTS

PG SGA.- PATIENT GENERATED SUBJECTIVE GLOBAL ASSESSMENT

PIF - PROTEOLYSIS – INDUCING FACTOR

QOL –QUALITY OF LIFE

RCT- RANDOMIZED CONTROL TRAIL

REE - RESTING ENERGY EXPENDITURE

SGA - SUBJECTIVE GLOBAL ASSESSMENT

TEE- TOTAL ENERGY EXPENDITURE

TNFα - TUMOR NECROSIS FACTOR ALPHA

TSF- TRICEPS SKIN FOLD THICKNESS

UBW - USUAL BODY WEIGHT

WT- WEIGHT

INTRODUCTION

INTRODUCTION

Nutrition has an important role in prevention and management of cancer. It also prolongs the life. It gives the essential elements needed for the cell survival. Providing better nutrition to cancer patient while on treatment helps to reduce the treatment related adverse effects and treatment delays.

Malignancy had an impact on food intake symptoms like; dry mouth, alteration in taste and smell of food, pain, dyspnoea and fatigue also affect food intake. Lung cancer is usually managed by chemotherapy and radiotherapy rarely by surgical resection. These treatments also affect food intake. These leads further deterioration of patient's nutritional condition.

Patients' performance status determines the treatment plan[1]. Reduced food intake affects the performance status and management options.

Prevalence of malnutrition in stage III/IV Lung cancer is 45-60%[2]. They experience a certain degree of anorexia and early satisfy before starting the treatment. These effects results in reduced food intake and more weight loss.

Under-nutrition leads to poor outcome in lung cancer patients. Malnourished patient had poor tolerance to treatment. Interventions that helps in improving nutritional status of patients with lung cancer results in better tolerability treatment and have prolonged life[3].

There is much evidence is available to state that good nutritional support results in better treatment outcome. But its use in clinical practices is limited. This

is due to lack of awareness among the health care professional and added cost of treatment.

The goal of nutritional therapy is to provide patient specific dietary counseling and to provide adequate food supplements by orally or parentraly. This approach is to be started at earlier phase of treatment that helps in improving the nutritional condition and performance status of the patient, which leads to better treatment tolerability and prolonged life.

EPIDEMIOLOGY OF LUNG CANCER

Cancer is one of the major non- communicable disease burden in India and world wide. In India, the projected number of cancer cases for the year 2020 are 11, 48,757, among them tobacco related cancers contribute 2, 25,251 cases. Estimated number of lung cancer, among men is 47,622 in the year 2015 and 51,193 in the year 2020. In female ICMR expects 14,705 cases in the year 2015 and 16,025 cases in the year 2020[4].

The prevalence of under nutrition in cancer patients is 30-85%. It is more in gastrointestinal, long and prostate cancer patients. In lung cancer patients prevalence of under nutrition ranges from 45-60%[2]. (Table 1)

PATHOPHYSIOLOGY OF MALNUTRITION IN LUNG CANCER

Lung cancer patients suffer from many symptoms like, breathlessness, cough, fatigue and pain. Chemotherapy and radiotherapy treatment can also cause, nausea, vomiting, mucositis, taste and smell alteration. These symptoms lead to poor intake of food, which leads to weight loss, malnutrition, poor response or tolerance to cancer treatment and impaired quality of life[5].(Figure 1)

Tumor and host cells compete with each other for nutrients which results in altered metabolism that leads to a state of accelerated starvation. This evolves into increased resting energy expenditure (REE) and energy insufficiency[6].

Cancer affects the metabolism of protein, fat and carbohydrate. This leads to hypermetabolic state, by altering the glucose and amino acid levels in the plasma. During this state there will be abnormal glucose production in the liver. Protein levels also altered in the muscle.

In healthy individuals, during starvation state glucose production occurs by using muscle protein. This process occurs slowly, so the lean body mass is maintained. This adaptive system is absent in malignancy that results in obvious reduction in protein level which leads to muscle atrophy. These metabolic alterations are mentioned in table 2. The results of cancer related under nutrition are explained in the figure 2.

Loss of Weight

Loss of weight is defined as under-nutrition in cancer patient. More weight loss seen in head and neck and gastrointestinal malignancies. Approximately 54% of patients suffer from weight loss prior to treatment[2]. It suggests that cancer related under nutrition starts even before the development of symptoms. More than 45% of cancer patients lose greater than 10% of their pretreatment weight during chemotherapy.

Lung cancer patients also often lose weight. The incidence varies form 45-69% with median percentage of weight loss is 6.5%[7]. The frequency of weight loss depends on the stage of the disease and number of anatomic sites involved with metastasis. Weight loss is more in advanced stage than in early stage[8].(Figure3)

Prognostic significance of weight loss before starting chemotherapy has been analyzed in many studies[9]. These studies were concluded that those patients who did not have loss of weight lived longer than who lost weight before starting treatment(Figure 4). These studies were done in patient with breast, colon, prostate and lung cancer.

Cachexia

Cancer cachexia is a severe form of malnutrition. It is a result of prolonged and persistent malnutrition. It usually occurs in advanced stage. Uncorrected cancer related symptoms like, nausea, vomiting, pain, dyspnoea and fatigue affects the food intake that leads to severe weight loss.

Cancer cachexia is a specific form of cancer associated malnutrition, usually occurs in later stage. The manifestations of cancer cachexia are increased weight loss, reduction in lean body mass and wasting of the muscles. Persistent nausea, weakness, early satiety, fatigue and depression are the other features present in cancer cachexia[10].

Understanding the development of cachexia is difficult.

The two explained reasons are;[11]

1. Under-nutrition due to reduced intake.

2. Alterations in protein, fat and carbohydrate metabolism in the host.

In cachexia, 60-70% of patients had reduced food intake[12]. Although anorexia contributes to malnutrition, cachexia is a result of tumor induced alteration in host metabolism[13]. In cancer patients, Insulin, which helps in utilizing Carbohydrate in muscle insulin sensitivity, is altered. Cancer is a negative energy balance state as a result of increased weight loss and reduced food intake.(Table2) More than 50-80% of cancer patients suffer from cachexia related morbidity and mortality[14]. Occurrence of cachexia depends on site of the malignancy. It is more common in gastrointestinal, lung and prostate cancers. It is rare in hematological and breast cancers.

Cachexia patients initially have minimal weight loss that progress to severe muscle wasting.

Cachexia stages are – pre-cachexia and cachexia syndrome.

Precachexia has minimal impact on survival, but cachexia syndrome severely affects the quality of life and survival. The pathway of cancer cachexia is shown in Figure 5.

Key features of cachexia are;[5]

1. Reduced food intake (<1500 kcal/day)
2. Loss of weight (>10%)
3. Elevated C-reactive protein > 10mg/l

In lung carcinoma, weight loss is a major prognostic factor. If weight loses is 30%, it indicates that they already lost 85% of total body fat and 75% of muscle protein.[13] This much weight loss results in weakness, reduced mobility, decreased organ function and finally ends in death.

If weight lose is >15%, this results in decreased organ function associated with 30% mortality[13].

Mediators of Cachexia

Many cytokines are released during the growth of tumor in the body. These factors also affect the host hormonal status. Both tumor related factors and host hormones together changes the carbohydrate, fat and protein metabolism. These factors also affect the intake of food which leads to muscle atrophy[15].(Table 3)

Host immune system produces a number of factors to combat this problem. Tumor necrosis factor alpha (TNFα) usually elevated. These factors contribute in decreased appetite, reduced food intake, increased breakdown of muscle protein loss of adipose tissue and loss of weight. TNF-α Promotes insulin resistance. [15,16]

Insulin, glucagon and cortisol are affected in cancer. Cortisol or glucagon is increased. Cachexia causes peripheral insulin resistance.

Cachexia patient had high levels of [13,16]

1. Proteolysis – inducing factor (PIF)
    - It induces the proteasome pathway that results in protein breakdown.
2. Lipid mobilizing factor (LMF)
    - It induces lipid degradation.

Two hallmark of cachexia are

1. Increased apoptosis as a result of increased PIF and TNFα
2. Excessive loss of skeletal muscle mass.

Event that occur in cancer cachexia are shown in table 4. Multi factorial causes of cancer cachexia are explained in figure 6.

Immune and Inflammatory markers:

Cancer is an inflammatory condition. Altered metabolism of cancer is a result of inflammatory response. In this condition many inflammatory cytokines are elevated. The level of these markers depends on the disease stage.

Commonly elevated markers are, C-Reactive protein, Tumor Necrosis factor- α, Interleukin-1, Interleukin 4, Interleukin- 6, IL-8 and IL-10.

C-Reactive Protein (CRP)

CRP is synthesized in the liver; it is under direct transcriptional control of IL-6 and indirect centre of IL-1, TNF-α. CRP is usually elevated in all inflammatory conditions including cancer. CRP levels usually raises >10mg/l in cancer patients.

STUDY

NUTRITIONAL ASSESSMENT AND INTERVENTION IN LUNG CANCER PATIENTS UNDERGOING TREATMENT

Nutritional, Screening, Assessment and Intervention:

Components of nutritional care

1. Screening
2. Detailed nutritional assessment
3. Nutritional therapy planning
4. Advise to patients and their family members
5. Reassessment
6. Evaluation of efficacy of nutritional intervention.

Comprehensive nutritional care in cancer is explained in figure 7.

Nutritional Screening

All cancer patients should be screened for nutritional status before starting any treatment.

The benefits of screening are:

1. Assessing baseline nutritional status.
2. Helps in preventing further reduction of nutritional status.
3. Helps to guide the selection of treatment.
4. Helps in maintaining the quality of life.

Screening Assessment Tools

Simple methods of nutritional screening are;

1. Percentage of weight loss
2. Reduction in BMI (<20 kg/m^2)
3. Low levels of serum proteins like,
    a. Serum albumin < 2.1 g/dl
    b. Serum prealbumin < 10mg/dl
    c. Serum transferrin < 100 mg/dl

Many tools are available for hospitalized patients. But only 3 tools validated in cancer patients. (Table 5)

While doing validation of these screening tools it should always correlated to the changes in the anthropometry, percentage of weight loss and serum protein levels.

1. Malnutrition screening tool
2. Mini Nutritional Assessment Tool (MNT)
3. Scored PG SGA.

1. The Malnutrition screening tool [17]

- It is a simple and short screening tool having 3 items.
- It is commonly used in cancer patients on radiotherapy and acutely ill patients.[18]

2. The Mini Nutritional Assessment tool (MNT)[19]

It has 18 questions. The questions are useful for screening and assessment.

The total score is 0-30 points;

Score <17 point – Malnutrition

Score 17-23.5 points – Risk of malnutrition.

It is mainly used to assess nutrition status of elderly population; it in use in cancer population is limited.

3. Score patient generated subjective global assessment (SPGSGA)[20]

This is the most validated tool to screen and assess the nutritional status in cancer patients.

It had 2 components,

First – Set of questions are completed by the patient. Second component is filled by health care persons.

First component of questions are related to patient food intake, physical activity, weight loss history and symptom status.

Second component of questions helps the health care person to assess the disease status, metabolic demand, like fever, edema and physical status of the patient.

Based on subjective assessment of (SGA) patient can be grouped into;[21]

SGA – A - Well nourished

B - Moderately nourished

C - Severe Malnutrition

Based on the numerical scores patient can be managed like,

Nutritional Triangle Recommendation[22]

Score 0-1 = No dietary counseling.

Score 2-3 = Advice is needed for patients and their family members

Score 4-8 = Dietary counseling is must

Score >8 = Needs nutritional intervention along with symptom control.

This PG-SGA score is highly reproducible [23,24]

- It is used to monitor the response of intervention
- It has high sensitivity and specificity
- It correlates with objective parameters

Nutritional Assessment:

After screening, risk groups are identified. They should under go detailed nutritional assessment. Nutritional assessment is done by trained dietician.

Nutritional Assessment includes

1. Measurement of Weight, BMI, % of weight loss, and other anthropometric parameters.
2. Measurement of serum proteins like albumin.
3. Collecting co-morbidity details of the patient.
4. Assessing symptoms related to cancer.
5. Assessment of daily dietary intake.
6. Assessment of physical and functional well being.
7. Assessment of patients and family belief.

Anthropometric Measurements

Varies parameters are used to assess body size and composition.

Body size assessment parameters are;

1. Weight
2. Ideal body weight
3. Adjusted body weight
4. Usual body weight
5. Percentage of weight loss
6. Height

Body compositions are assessed by;

1. Triceps, skin filed thickness, and mid-upper arm circumference.
2. Measurement of mid arm muscle circumference
3. Body Mass Index (BMI)
4. Lean Body Mass (LBM)
5. Bioelectric Impedance Analysis (BIA)

Measurements

1. Weight
    - Weight should be measured during every visit.
    - Same weighing scale to be used every time.
    - Any changes in the weight indicate the health status.

2. Usual Body Weight (UBW)
    - This is the weight patient remembers.

3. Percentage of Weight loss

    It is calculated from the formulae.

$$\%\ \text{Weight Loss} = \frac{\text{Usual Weight} - \text{Present Weight}}{\text{Usual Weight}}$$

Significant Weight Loss :

Time Period	Significant Loss	Severe Loss
1 Week	1-2%	>2%
1 Month	5%	>5%
3 Months	7.5%	>7.5%
6 Months	10%	>10%

Height:

- Height of the patient usually measured at the first visit.
- Height usually unaffected in Adults with malnutrition.
- Height is measured by using height measuring device or measuring tape placed on the wall.

Triceps: (Skin fold or Mid arm circumference)

Triceps skin fold thickness – measure the subcutaneous fat. Triceps skin fold reflects the body fat change.

TSF changes can be assessed every 3-4 weeks.

Mid Arm Circumference (MAC)

It is measured at mid point between acromian process of scapula and olecrenon process of ulna by using measuring tape.

Mid Arm Muscle Circumference (MAMC)

It is calculated from mid arm circumference and triceps skin fold thickness.

MAMC (CM) = MAC (CM) – (π x TSF(mm))

Body Mass Index (BMI)

BMI = Weight / Height (m) ^{2}

BMI = highly correlate with body fatness

Normal BMI limit for Indians in

Underweight = <18.4 kg/m^2

Normal = 18.5 – 22.9 kg/m^2

Overweight = 23 – 24.9 kg/m^2

Obese = >25 kg/m^2

Body composition

- Body composition measurements are better marker of nutritional status of patient.
- It is useful to give patient specific nutritional counseling. [25]
- It is useful to monitor the response to nutritional therapy.

- Commonly used measurements are Lean Body Mass and Bone Mineral Density.

Lean Body Mass or Lean Body Weight

It refers to the weight of all body organs, bone and muscles without fat.

Formulae

For Men : LBM = (0.32810 x Wt) + (0.33929 x Ht) – 29.533.6

For Women : LBM = (0.29569 x Wt) + (0.41813 x Ht) – 43.293.3

Wt – Body weight in kilograms.

Ht – Body height in meters.

Nutritional Intake Assessment

Food intake assessment includes

1. Details about regular diet
2. Frequency of intake
3. Intake of snacks
4. Amount of food intake
5. Changes in the dietary pattern
6. Details of food restrictions
7. Details of dietary supplement

Patients' symptom related assessment includes

1. Presence of nausea or vomiting
2. Difficulty in chewing and swallowing
3. Taste and smell alteration

Food intake assessment methods are

1. Random weekly, food intake.
2. 24 hr recall
3. 2 week days food intake + 1 weak end food intake.

The 24 hours dietary recall is the gold standard method to collect the dietary data.

The advantage and disadvantage of various dietary methods are mentioned in table 6.

Biochemical Markers:

Protein status

To assess the nutritional status serum levels of hepatic proteins like albumin, transferring and pre albumin are measured. They indicate the severity of illness and correlate with morbidity and mortality. Prealbumin levels indicate acute nutritional repletion. Serum proteins level indirectly gives the information about the visceral protein levels. If food intake is less, hepatic synthesis also reduced.

Half life of Albumin – 15to 20 days

Half life of Transferrin – 8 days

Half life of Pre-albumin – 2 to 3 days.

1. Serum albumin

    - Commonly used prognostic marker.
    - Half life (15-20 days)
    - It is slowly respond to dietary intervention.
    - It is as baseline nutrition marker.[26]
    - Predicts the prognosis in colorectal cancer[27]
    - But it is not useful to assess the short time changes after nutritional intervention.

2. Transferrin

    - It is synthesized in the liver.
    - It has short and half life (8-10 days)
    - It acts as an iron transporter.
    - It levels are affected by renal impairment, surgery.

Since serum transferrin levels are reduced in chronic inflammatory conditions and its use as a marker of nutrition status are limited.

3. Prealbumin

It is used to assess the short-term nutritional intervention since it has 2-day half life.[28] It is unaffected by hydration status. Its level may be reduced with hepatic dysfunction, acute catabolic stress, sepsis, surgery, and trauma.

Risk of malnutrition depends on the level of prealbumin,

Level <100 mg/l – Severe risk

Level 100 to 170mg/l – Moderate risk

Level > 170 mg/l – No risk

Relation between C-Reactive Protein & Prealbumin [29]

During cancer and other inflammatory conditions acute phase proteins like C-Reactive Protein (CRP), α1-acid glycoprotein and fibrinogen are elevated. At that time, pre albumin levels are reduced due to reprioritization of synthesis of CRP in the liver.

Nutrition Intervention

Dietary interventions are,

1. Nutritional counseling
2. High caloric, oral protein supplements
3. Enteral and parentral nutrition.

In cancer patient, the type intervention is decided by the following factors.

1. Baseline nutritional status or deficit

2. Ability of oral intake
3. Gastro intestinal tract integrity
4. Performance status
5. Treatment side effects
6. Family background
7. Cost of the intervention

Estimation of Nutritional needs

Calorie need:

Calorie needs depends on the histology of the cancer. Some cancers are considered hyper metabolic based on Basal Energy Expenditure (BEE). Hepatocellular carcinoma and pancreatic tumors are hyper metabolic cancer.[30.31]

Lung cancer, colorectal, esophageal and liver metastasis are not considered, to have hyper metabolic state based on BEE.[32,33]

Calorie expenditure is determined by calculation of basal metabolic rate by direct or indirect calorimetry.

These methods are costly and are available only in few laboratories.

Harris & Benedict developed simplex method to calculate the expected metabolic rate (Table 7). To derive the predicted total energy expenditure (TEE) Harris-Benedict equation is multiplied by stress factor (Table -8)[34]

Determination of calorie needs in cancer patient.[35]

For weight maintenance = 1.15 x BEE kcal/d

For repletion and anabolism = 1.5 x BEE kcal/d

Oral supplements that provide 1 kcal/ml is not useful to improve the nutritional status. But supplements that gives 1.5 kcal/ml helps in maintaining weight.[36]

Measurement of protein needs

Cancer is a hyper metabolic state. Measurement of urinary nitrogen loss is the best method to calculate protein requirements. This method is impractical and difficult to collect 24 hr urine and fecal samples for calculation of total nitrogen output.

The degree of protein loss and metabolic stress factors determine the amount of protein needed.

For well nourished individual – 0.8 to 1.0g/kg IBW

For cancer patients - 1.5 to 2g/kg IBW

IBW – Ideal Body Weight

Table 9 gives the details of protein requirement calculation.

Routs of Nutritional Intervention

1. Oral route
2. Enteral nutrition
3. Parenteral nutrition

Oral Route [37]

- Less expensive and most preferred mode of intake.
- Home made diet plans can be advised.
- Many energy dense supplements are available.
- This oral route is better tolerated by patient.
- It improves appetite
- It maintains gut integrity

Enteral Nutrition[38]

- It is the method of delivering nutrients into gastro intestinal tract by tubes or catheter. (Figure -8)

- It is mainly indicated in patients who cannot eat sufficiently.

Choice of external feeding determined by

1. Clinical condition of the patient
2. Aspiration risk
3. Duration of feeding

Nasogastric Tube
Nasoduodenal Tube } = useful for short term feed
Nasojejunal Tube (<3-4 Weeks)

If risk of aspiration is present Nasoduodenal and nasojejunal tube is preferred.

Long term feeding is more than 3-4 weeks then feeding tube enterostomies are advised.

Methods :

- Esophagostomy
- Gastrostomy
- Jejunostomy

If risk of aspiration is present jejunostomy is the best method.

Parentral Nutrition:[39]

Indication:

1. Reduced food intake >7 to 10 days.
2. Loss of weight
3. Patient who could not take food by oral or enteral route.

Quality of life QOL:

Quality of life is important parameter analyzed in clinical studies. QOL depends on disease status, treatment, and its toxicity.

Cancer treatment reduces the tumor burden and improves the quality of life.

But treatment related toxicity may affect the patient quality of life. This can be overcome by anticipating and making necessary measure to reduce the toxicity.

Other measures are;

1. Changing the treatment plan
2. Reducing the doses
3. Providing supportive measures
4. Changing the route of drug administration

Now most of the cancer patients live longer even with disease, which is controlled by medication. They should lead normal life without or minimal toxicity from the treatment. So assessing quality of life is very important in ontological treatment.

Commonly used QAL questionnaire in lung cancer studies are (table-11);

1. EORTC C-30 [40]
2. Lung Cancer Symptom Scale [41]
3. FACT-L [42]

1. EORTC – QLQ 30, QOL-LC 13

- It is specific for lung cancer.
- It is used in most of the lung cancer trials.

2. Lung Cancer Symptom Scale (LCSS)

- It is more specific for lung cancer.
- It addresses specific symptoms related to lung cancer.

3. FACT-L Functional Assessment of Cancer Therapy – Liz.

- It has 44 items
- It is available in 8 languages
- It is currently used in many phase 2&3 clinical studies that is related to lung cancer.

REVIEW OF LITERATURE

LITERATURE REVIEW OF SIMILAR STUDIES

Guarcello et at. [43] did a study on EPA-enriched oral nutritional support in patients with lung cancer. He analyzed the benefit of EPA riched, oral supplement in lung cancer patients.

The investigator enrolled 46 malnourished lung cancer patients on chemotherapy . The study group (n=26) was advised to take 2 cans a day of an EPA-enriched oral supplement for 60 days. The control group (n=20) was advised to take 2 cans a day of an iso-caloric, iso-nitrogenous, oral supplement which did not have EP. Weight gain, appetite, energy and protein intake, quality of life, biochemical parameters like C-reactive protein, transferring and prealbumin levels are measured at the time of enrolment, at 30 days and at 60 days in both groups. At the end of the study he concluded that lung cancer patients who received EPA riched oral supplement had significant benefit in the analyzed parameters and reduction of C-reactive protein levels.

BS van der Meij et al[44] did RCT on the role of supplementation of n-3 polyunsaturated fatty acids (PUFA) in lung carcinoma patients during treatment. He assessed the quality of life, performance status, handgrip strength and physical activity . He enrolled 40 patients totally and randomized to study and control groups. The study group received PUFA 2.02g EPA and 0.92g DHA per day. The control group received iso-caloric supplements.

He analysed the QOL, PS and hand grip strength and physical activity of the pts in both group. At the end of the study, the interventional group had a

significantly better analytical parameters after 5 weeks. No difference observed in hand grip strength between the groups. He concluded n-3 PUFA may beneficially affect QOL, PS and physical activity in lung cancer patients.

Nicole kiss et al,[7] did a systemic review on studies related to dietary counselling (DC), oral supplements (OS) during treatment in lung cancer patients up to March 2012. In this review he included 3 RCT, 1 historical control and 1 case series.

He examined, if DC and OS during treatment affects the nutritional status, functional status, QOL, and treatment outcome. He found that, DC consistently improves the dietary energy and protein intake during treatment. Some low level evidence suggested that DC or OS may reduce percentage of wt loss and maintain the nutritional status during treatment. Only limited evidence seen on effect on QOL and functional status and no evidence located for treatment outcome and survival in lung cancer patients.

Another multicentric RCT done by **C Baldwin et al**[45] with the aim of the effect of diatetic and oral energy dense supplements in relation to survival and QOL in patients with lung and GI malignancies receiving palliative chemotherapy. He enrolled a total of 358 patients, including 254 GI cancer patients and 81 lung cancer patients in this study and they were randomized to receive either 1. No intervention, 2. Nutritional supplements (2550 Kj/day and vitamins), 3. Dietary advice and 4. Diatary advice and nutritional and vitamins supplements for 6

weeks. He also assessed QOL at 6 and 26 weeks by using EORTC C30. Follow up period was 1 year.

The one year survival for all patients combined was 37.8% and there were no survival benefits in between the intervention groups. There is no significant difference in improvement in QOL in all groups.

The same investigator did a meta-analysis [46] on oral nutrition interventions in undernourished cancer patients. He analyzed 13 studies which include 1414 patients with various cancers including lung cancer. The end points which analyzed were nutritional and clinical outcome and QOL with oral nutritional interventions.

Finally he found that the dietary counselling and oral supplements were resulted in weight gain and increased energy intake compared with routine care but nutritional interventions had no benefit on survival.

Study

Nutritional assessment and intervention in lung cancer patients undergoing treatment

Aims and Objectives

The aim of the study is to find out if dietary counselling (DC) and Nutritional intervention before, and during chemotherapy with or without radiotherapy treatment helps to reduce weight loss , improve quality of life and treatment tolerability in patients lung cancer.

Primary Objectives

1. Assessment of nutritional status in lung cancer patients by using parameters like appetite, PGSGA score, percentage of weight loss, Lean Body Mass ,Mid Arm Muscle Circumference and biochemical markers - C-Reactive Protein and Prealbumin.

2. Analysis of outcome of nutritional intervention after 8weeks in terms of Energy intake, Weight gain and Quality of Life.

Secondary Objectives

Assessment of chemotherapy tolerability and toxicity.

ARMS OF THE STUDY

ARM 1: **USUAL CARE** which consists of one-to-one dietary counselling in person once prior to starting and every cycle of chemotherapy for between 15 to 30 minutes each. This patients takes usual diet only.

ARM 2: **MEDICAL NUTRITION THERAPY**. This will involve indivualised one-to-one dietary counselling in person once prior to starting , and every cycle of chemotherapy. Each session will be between 15 to 30 minutes duration depending on the degree of nutritional issues identified. Patients in this group advised to take FDA approved nutrient dense high protein oral supplement that provides 450Kcal and 34 g protein per day for minimum of 8weeks.

METHODOLOGY

METHODOLOGY

Materials and Methods:

Study period: From October 2012 to February 2013

Study design : Randomized control trial

ELIGIBILITY CRITERIA:

Forty nine patients with lung cancer who satisfied the following eligibility criteria were included in this study.

1. Age >18 years
2. Gender : Both male and Females
3. Histologically diagnosed of lung cancer on chemotherapy with or without Radiotherapy.
4. Performance status 3 or less according to ECOG score
5. Life expectancy >2 months

EXCLUSION CRITERIA:

1) Lung cancer patients on supportive care only.
2) Performance status -4 according to ECOG score.
3) Patients with a cognitive impairment or psychiatric illness.

PRETREATMENT WORK UP

1. Complete clinical examination
2. Complete haemogram
3. Biochemical investigations to assess renal function and liver function.
4. Histopathological documentation
5. Chest X-ray
6. CT Scan Chest and abdomen
7. Skeletal survey / Bone scan

ASSESSMENTS OF PARAMETERS:

Appetite was assessed by visual analogue scale (0 = lack of appetite; 100 = hunger). (Figure 10)

Performance status was recorded by using ECOG score . (Table 12.)

Nutritional risk assessment was done by PGSGA score at time of initial presentation and every cycle of chemotherapy. (Figure 11)

Anthropometric indices

1. Height (m), - measured by measuring tape fixed on the wall.
2. Weight (kg), - measured by digital weighing scale.

3. Percentage body weight loss measured by

$$\frac{\text{UBW} - \text{current weight} \times 100}{\text{UBW}}$$

UBW – USUAL BODY WEIGHT

4. Body Mass Index - measured by

BMI = WEIGHT (kg) / HEIGHT $(m)^2$

5. Lean Body Mass - measured by

For men : LBM = (0.32810XWT)+(0.33929XHT) - 29.5336

For women LBM = (0.29569XWT) +(0.41813X HT) – 43.2933

6. WT- Body weight in kilograms, HT – Body height in meters

7. Triceps skin fold thickness,

8. Mid arm muscle circumference (calculation based on mid arm Circumference –MAC and Triceps skin fold thikness (TSF)

MAMC = MAC (cm) – (0.314 X TSF(mm))

Daily dietary intake was calculated based on the 24 hour recall provided by the patient. This data on food intake would be translated into energy and protein

intakes by means of specific tables validated for Indian foods by National Institute of Nutrition (NIN) Hyderabad.

Quality of life was determined via Functional Assessment of Cancer Therapy - Lung questionnaire, (FACT-L version 4) before and every cycle of chemotherapy.

Chemotherapy toxicity was assessed by Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0

Biochemical analysis like serum levels of CRP and prealbumin levels were measured before and at 8 weeks of treatment.

BLOOD SAMPLE COLLECTION

Two ml of peripheral blood was collected in tubes with no anticoagulant at the time of starting first cycle of chemotherapy and 3rd cycle of chemotherapy (8 weeks after first cycle of chemotherapy). From this serum is extracted by centrifugation and stored in the Institute of Biochemistry at – 20^{0} C. This sample is used for analysis of C - reactive protein and Prealbumin. These proteins are quantitatively analysed by immunoturbidimetric method by using Merck Micro Lab 300 semi automated analyser in the Institute of Biochemistry in our hospital.

STATISTICAL METHOD

We used paired‘t’ test statistical method to compare the measured parameters in this study by using SPSS version 16 software.

RESULTS AND ANALYSIS

STUDY ANALYSIS AND RESULTS

Out of the 782 cancer patients treated between October 2012 and February 2013 in our Medical Oncology Department, 76 (9.7%) patients are presented with Lung cancer. PGSGA score 8 or more at time of enrolment was used to select the patients both in the usual care (control arm) and medical nutritional therapy (study or interventional arm) groups. Total of 49 Lung cancer patients who met the eligibility criteria entered into this study. Among them 6 patients were removed from the study due to early death, poor follow up and poor compliance to intervention.

PATIENTS CHARACTRISTIC

The age ,sex and histology distribution are matched in both groups. Patient base line characters are given in the table 13.

In usual care group 22 patients (16 men, 6 women) were included. Median age of this group was 56 years (range 32- 75years). Twenty patients were diagnosed to have NSCLC and 2 patients had a diagnosis of SCLC.

Twenty one patients (16 men, 5 women) were randomly assigned in the Medical Nutritional therapy(MNT) group. Their median age was 58 years (range 50- 66years). Twenty patients were diagnosed to have NSCLC and one patients had a diagnosis of SCLC.

In this study one non smoker developed adenocarcinoma and all others used to have some form of tobacco for more than 30 years. Twelve patients had

type 2 diabetes mellitus (usual care 6, MNT 6). Thirteen patients were in stage III (Usual care 8, MNT 5), 29 patients (usual care 14, MNT 15) are in stage IV. Among the stage IV 19 patients had pleural effusion, 6 patients had brain metastasis, 2 had liver metastasis and 1 with bone metastasis.

One patient with stage IB had left upper lobectomy followed by adjuvant chemotherapy. Thirteen patient received concurrent chemoradiation. Eighteen patients received chemotherapy alone. Six patients received whole brain radiotherapy followed by palliative chemotherapy.

Most commonly used chemotherapy regimen was cisplatin and etoposide (usual care 20, MNT 19). The other regimen carboplatin with Paclitaxel was used in 4 patients. Both groups tolerated the chemotherapy.

We assessed treatment related toxicity by using Common toxicity criteria for Adverse Events version 4. Twenty patients (Usual care 11, MNT 9) experienced grade 3 fatigue, 7 patients experienced grade 3 cough, 9 patients had grade 3 nausea and vomiting. Four patients received blood transfusion for grade 3 anemia. The toxicity were evenly distributed in both groups.

1.

2.

3. AGE DISTRIBUTION (Figure 14)

In this study in usual care group we enrolled patients between 32- 75 years of age. The median age was 58 years and most (63.6%) of the patients in 5th &6 th decade. In medical nutritional therapy group patients age ranges from 50- 66 years.that is 100% are in 5th & 6th decade . The median age in this group was years.

AGE (YEARS)	USUAL CARE (N=22)	MEDICAL NUTRITIONAL THERAPY (N=21)
31- 40	2	0
41-50	5	3
51-60	7	12
61-70	7	6
71-80	1	0

4. SMOKING PATTERN (Figure 15)

Voluntary smoking is the most common cause for lung cancer development. In both groups voluntary smokers are more (>60%)

SMOKING PATTERN	USUAL CARE (N=22)	MEDICAL NUTRITIONAL THERAPY (N=21)
VOLUNTARY	14 (63.3%)	15(71.4%)
INVOLUNTARY	4	4
SMOKELESS TOBACOO USE	4	1

NON SMOKER	0	1

3. TOXICITY DISTRIBUTION

In our study toxicity were analysed according to CTCAE version. In both group patients had comparable toxicity.

TOXICITY GRADE 3/4	USUAL CARE (N=22)	MEDICAL NUTRITIONAL THERAPY (N=21)
ANEMIA	2	2
NAUSEA	5	4
VOMITING	3	2
DIARRHEA	2	4
FATIGUE	11	9
BRONCHIAL OBSTRUCTION	3	2
BRONCOPULMONARY HEMORRHAGE	1	1
BRONCHIAL SPASM	3	2
COUGH	5	6
DYSPNEA	7	6
PLEURAL EFFUSION	10	9
PLURITIC PAIN	3	2
PNEMONITIS	4	2
VOICE ALTERATION	2	2

WHEEZING	5	4

APPETITE:

During every visit for chemotherapy patients appetite was evaluvated by using Visual Analog hunger scale. After nutritional counselling mean appetite value is increased in usual care group. In the same way MNT group patients oral protein supplementation and nutritional counselling improves the appetite.

PATIENT-GENERATED SUBJECTIVE GLOBAL ASSESSMENT SCORE :

We included the lung cancer patients who had base line PGSGA score of 9 or more in this study. These patients are randomized to usual care group and MNT group. PGSGA score was recorded during every visit.

In usual care group the base line mean PGSGA score was 12.95 which drops to mean value of 9.86 at 8 weeks. In MNT group also the mean value of PGSGA score was dropped from 13.19 to 9.61. which shows not only the nutritional supplementation but also nutritional counselling improves the nutritional outcome.

ANTROPOMEMETRIC MEASUREMENTS: RESULTS

The weight, triceps skinfold thickness (TSF) and midupper arm circumference (MUAC) were measured every visit. Height was measured at first visit .

WEIGHT :

In usual care group, the mean weight was 47.46 kg at first visit , it increased to 48.06 Kg at 8 weeks. In MNT group , the mean weight was increased from 46.8 Kg to 48.21kg at 8 weeks. Both nutritional counselling and intervention improves the weight gain significantly (p =0.00) in lung cancer patients.

PERCENTAGE OF WEIGHT LOSS AT THE TIME OF ENROLMENT.

At the time of enrolment 28 patients (usual care 14, MNT 14) had > 10% weight loss.

Percentage of wt loss	Usual care(N=2)	MNT(N=21)
<5% loss	0	1
5-10% loss	8	6
11-20%	12	10
>20%	2	4

LEAN BODY MASS

The mean lean body mass in usual care patient at Ist visit is 39.82kg , at 8 th week it is 40.15 kg. In MNT patients LBM at Ist visit is 39.54kg and at 8 th

week it is 40.38 kg. Both nutritional counselling and intervention improves the lean body mass significantly (p =0.00).

MID-UPPER ARM MUSLE CIRCUMFERENCE (MAMC)

Mid-arm muscle circumference (MAMC) was calculated with the TSF and the MUAC measurements (MAMC (cm) = MUAC (cm) - (π x TSF (cm))). In ususal care group 0.11cm decrease in mean MAMC, but it is not statistically significant. In MNT patients there is a gain of 0.33cm in MAMC.

CALORIE AND PROTEIN INTAKE

In usual care patients the energy and protein requirement is calculated as per Ideal Body Weight. They advise to take 30 kCal/ kg and 1.5g/kg protein per day. Deitary plan was made my registered dietician working in the Institute of Diabetology . Each visit dietary intake was recorded by using 24 hr recall chart. The mean energy intake was improved from 1719 kcal/day to 1859 kcal/day at 8 weeks. The protein intake was improved from 33.88g/d to 36.86g/d.

In MNT group patients in addition to the nutritional counselling, and diet plan they advise to take protein rich energy dense oral supplements. While adding 24 grams of these supplements in 200ml of milk provides 223 kcal and 17 gram of protein. They advised to take the same amount of supplement in the milk twice a day. The mean energy intake was improved from 1540kcal/day to 2060 kcal/day at 8 weeks. The protein intake was improved from 33.88g/d to 66.09g/d. At 8 weeks.

QUALITY OF LIFE ASSESSMENT

Functional Assessment of Cancer Therapy-Lung (FACT-L), was used which includes a questionnaire based on physical, social, emotional, and functional wellbeing, and lung cancer symptoms . Tamil language version was used in this study. FACT-General ,Physical well being (PWB),Functional well being (FWB) and LCS was assessed every visit. In usual care group FACT-G, PWB and FWB stastically improved from baseline. In MNT group FACT-G, and PWB stastically improved from baseline, but FWB is not improved.

BIOCHEMICAL PARAMETER ASSESSMENT

We used C-Reactive protein as marker of inflammation, and Prealbumin as nutritional marker. In usual care group the baseline CRP was reduced from 16.26mg/dl to 14.06 mg/d at 8 weeks. In MNT group baseline CRP was reduced from 16.55mg/dl to 13.05 mg/d at 8 weeks. The reduction was not statistically significant.

Serum Prealbumin base line value in the usual group dropped from 65.03 mg/dl to 44.78 mg/dl. In MNT group the prealbumin base line value improve from 49.05 mg/dl to 58.21mg/dl. The pre albumin drop in usual care and rise in MNT patients was not statistically significant.

The mean difference of the above parameters in the uasual care group were compared with MNT group. There is no statistical difference in appetite, PGSGA, anthropometric measurements, energy, protein intake Quality of life and bio chemical parameters.

DISCUSSION

Discussion

Lung carcinoma is the major cause of cancer death worldwide . Traditionally, 8% to 84% of the patients would suffer from under nutrition throughout the disease course. Malnutrition leads to poor our come. Oncology nutrition is the new subspeciality. Nutritional intervention will improve the outcome.[47] Lung cancer patients are suffering from under nutrition. The prevalence of malnutrition in lung cancer patients at various stages of disease and treatment ranges from 45 to 69%, with a median weight loss of 6.5% reported compared to usual weight [7].

The reasons are, most of the lung carcinoma patients are presented at advanced stage with high tumor burden and hypermetabolic state and high energy is spent for respiratory effort.

In our hospital nearly 250 to 270 newly diagnosed lung cancer patients are being treated every year. Among them 40 -60% are malnourished and they lose their weight during treatment. Many studies addressed nutritional assessment and intervention in gastrointestinal malignancies and in the Head and Neck cancer. Only few studies are done in lung cancer patients.

So we decided to study the nutritional assessment and intervention in lung cancer patients undergoing in our Medical Oncology Department.

We enrolled 49 patients in this study from October 2012 to February 2013. Among them 6 patients dropped from the analysis duo to early death, poor follow up and non compliance to nutritional advice and intake.

We assessed the nutritional status of the patients by using Patient-Generated Subjective Global Assessment score. The score 9 or more are randomized to usual care group who received dietary counseling only and Medical Nutritional Therapy group who received energy dense protein supplementation which provide 450 kcal/day and 34 g/day of protein in addition to dietary counseling. The results are compared in table 12 and 13.

Weight loss is most commonly observed symptom in lung cancer which adversely affect the outcome. Loss of weight is one of the predictor of shorter overall survival lung carcinoma patients. Lung cancer patients who had weight loss > 10% showed more symptoms, delay in chemotherapy, anaemia poor responses to chemotherapy and shorter survival .[48]

In our study, at the time of enrolment, 14 patients had percentage of weight loss between 5-10%, 22 patients in the range of 11-20%, and 6 patients had > 20% weight loss. In western standard, the mean weight loss in lung cancer is 6.5%[7]. **Nicole kiss et al[7]** and **Baldwin et al[46]** showed that the dietary counselling improves the weight gain and energy intake. In our study also, after intervention (either with dietary counselling (DC) or oral supplementation) there is a statistically significant weight gain in both the groups. Hence at the least DC is must to improve weight gain and outcome and to improve QOL. Weight gain and increased energy intake

improves the Lean Body Mass and Mid Arm Muscle Circumference values. (P=0.00)

PG-SGA score can be used as an objective measure to demonstrate the outcome of nutrition intervention.(?). The PGSGA score is a validated nutritional screening and assessment tool used in our study. Here, the PGSGA score in usual care group was 12.95 (ranges from 9 to 19) which was found to be reduced to 9.86(ranges from 7 to 14) and in the MNT group, the initial score was 13.19 (ranges from 9 to 210 and it was reduced to 9.61 (ranges from 7 to 13) at 8 weeks. The reduction was found to be significant in both groups (p=0.00).

The energy intake is reduced in cancer patients because of alteration in taste sensation, loss of appetite, early satiety and toxicity to the treatment. And also energy insufficiency occurs because of increased metabolic activity and resting energy expenditure. **Nicole kiss et al** [7] and **Baldwin et al** [46]showed that the dietary counselling improves the energy intake. In our study, the mean energy intake is improved from 1719 Kcal/day to 1859 Kcal/day (p=0.00) in usual care group and in MNT group it increased from 1540Kcal/day to 2060Kcal/day (p=0.00). In the same way the mean protein intake is increased from 33.88g/day to 36.86 g/day in usual care group (p=0.00). In MNT group it is increased from 33.88g/day to 66.09g/day (p=0.00).

In our study we used FACT-L QOL questionnaire to assess the quality of life. The FACT-G is the total score of physical, functional and social well being. In our study we have analyzed all above said parameters FACT-G score and Physical

well-being score are statistically improved at the end of 8 weeks of intervention(p=,0.05) in both the groups. The functional well being was improved in control group (p=0.007) but not improved in study group (p=0.729). Most of the studies were done using EORTC C30 tool and there is no study available to compare the results in lung cancer patients enrolled in nutritional studies.

Prealbumin, is a serum protein used to assess the nutritional status. It is more sensitive to changes in protein-energy status than albumin. Its concentration closely reflects recent dietary intake rather than overall nutritional status. (/).

In our study, for the usual care group, at the time of enrolment the mean pre-albumin value was 65.03 mg/dl (range from 15.1 to 99.3 mg/dl) which decreased to 44.78 mg/dl (range from 9.2 to 231.7 mg/dl) at 8 weeks and the difference is not significant(p=0.804). In MNT group, initially the mean pre-albumin value was 49.05mg/dl (ranges from 14.3 to 220.3 mg/dl). The value increased to 58.21mg/dl (ranges from 21.6 to 234.7 mg/dl) at 8 weeks and this increase is not statistically significant (p=0.67).

Chronic inflammatory disease, such as cancer, can produce a persistent increase in the serum concentration of CRP. Weight loss is the nutritional indicator most related to serum CRP [49]. Studying patients with esophagus and stomach cancer, **Deans et al [50],** found the following variables to be determinant of weight loss: dietary intake, high serum CRP concentration and stage of the disease. The attenuation of systemic inflammatory response has been studied as a way to improve nutritional status. Supplementation with omega-3 fatty acids may help

stabilize weight in cancer patients with oral dietary intake who exhibit intentional, progressive weight loss. Initially in usual care group, the mean CRP value was 16.26 mg/dl (ranges from 9.73 to 26.52 mg/dl) which is reduced to 14.06 mg/dl (ranges from 18.60 to 22.41 mg/dl) in 8 weeks (p=0.267). In MNT group, initial Mean CRP value was 16.55 mg/dl (ranges from 11.26 to 26.36 mg/dl) which is reduced to 13.04mg/dl (ranges from 7.91 to 21.46 mg/dl) at 8 weeks which is highly significant (p=0.006).

In our study we used FACT-L QOL questionnaire to assess the quality of life. The FACT-G is the total score of physical, functional and social well being. In our study we have analyzed all above said parameters FACT-G score and Physical well-being score are statistically improved at the end of 8 weeks of intervention(p=,0.05) in both the groups. The functional well being was improved in control group (p=0.007) but not improved in study group (p=0.729). Most of the studies were done using EORTC C30 tool and there is no study available to compare the results in lung cancer patients enrolled in nutritional studies.

Even though there is significant differences in the mean values between the initial period and at 8 weeks of intervention among the group itself but there is no statistically significant differences noted between the usual group and the Medical Nutrition Therapy group in all analyzed parameters.

Baldwin et al [45] finally stated in his study that the use of only energy dense high protein supplements and/or dietary advice have not shown any improvement

in the outcome. In our study also shows that there is added benefits of using oral protein supplements along with dietary counselling.

M. Guarcello et al,[43] done a study with EPA enriched oral nutritional supplement seems to be effective in improving nutritional status and quality of life in compare with iso-caloric and iso-nitrogenous non EPA enriched oral supplements alone. In this study he showed that there is a significant increase in body weight, energy and protein intake, QOL, appetite, pre-albumin and transferring as well as there is significant reduction in C-reactive protein levels. EPA reduces the inflammatory cytokine production and there by reduces the wasting in cancer patients.

BS van der Meij et al [44] used n-3 PUFA along with protein supplements have shown the improvement in QOL, physical activity and performance status. The PUFA from the fish oil has an immune modulating effect by forming the mediators with a lower pro-inflammatory and immunosuppressive effects.

In our study both group of patients tolerated the chemotherapy well and completed the course without any delay. The toxicity were evenly distributed and tolerated well in both groups.

In summary, in our study, the dietary counselling alone or dietary counselling with oral supplements definitely gives a benefit in improving appetite, weight gain, energy intake, and QOL separately. But while comparing both the groups, there is no additional benefit in adding oral supplements with dietary counselling. These results are comparable with the studies done with dietary

counselling with or without high energy oral supplements. Both group of patients tolerated the chemotherapy and its toxicity well and completed the course without any delay. Some studies have shown the true benefits of using oral supplements containing immune modulating nutritional substances like n-3PUFA and EPA with promising effects.

CONCLUSION

CONCLUSION

In our study, about 65% of the enrolled patients had more than 10% weight loss at presentation which is a worst scenario.

Dietary counselling alone or dietary counselling with oral supplements definitely gives a benefit in improving appetite, weight gain, energy intake, and QOL separately.

Both group of patients tolerated the chemotherapy and its toxicity well and completed the course without any delay.

In conclusion, all patients with lung cancer definitely need dietary counselling at least to improve the weight gain and treatment tolerability.

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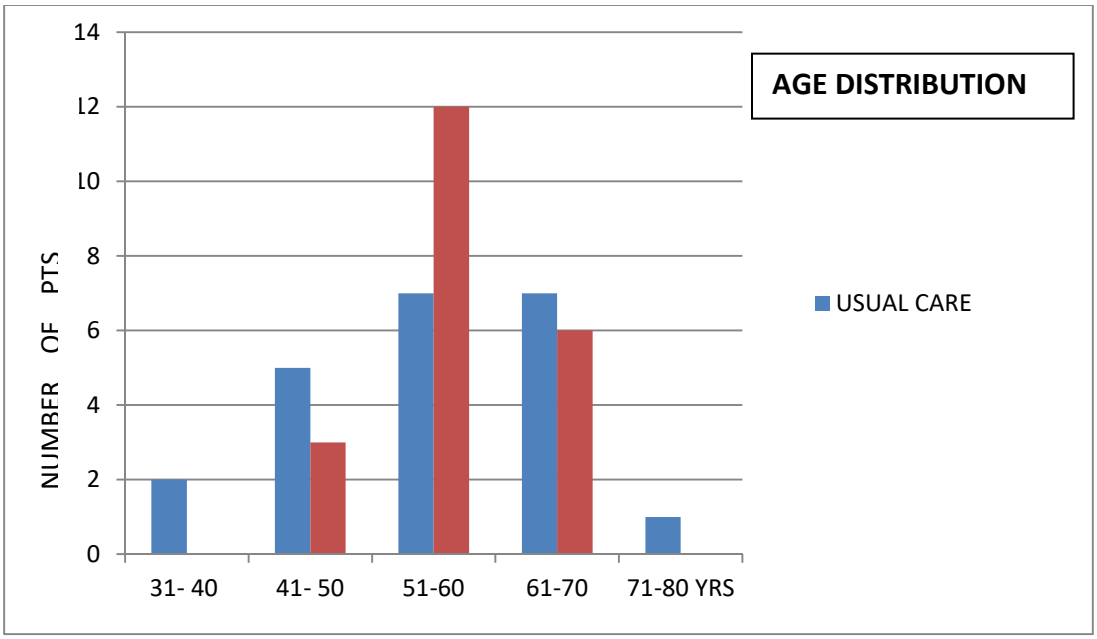

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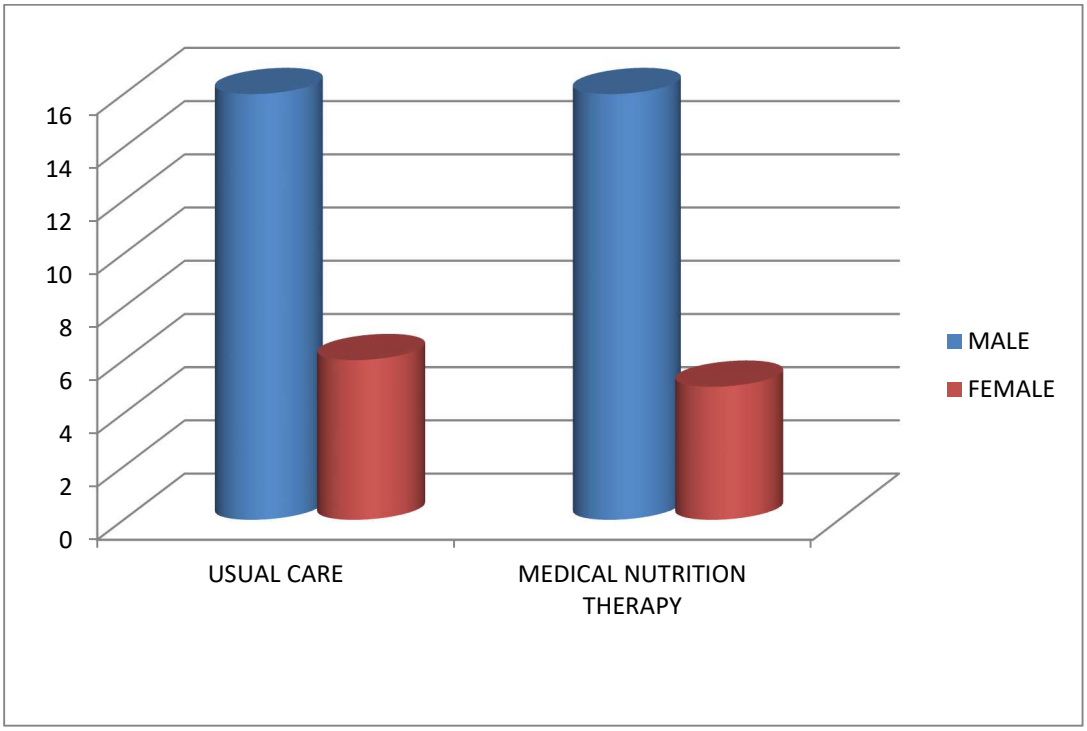

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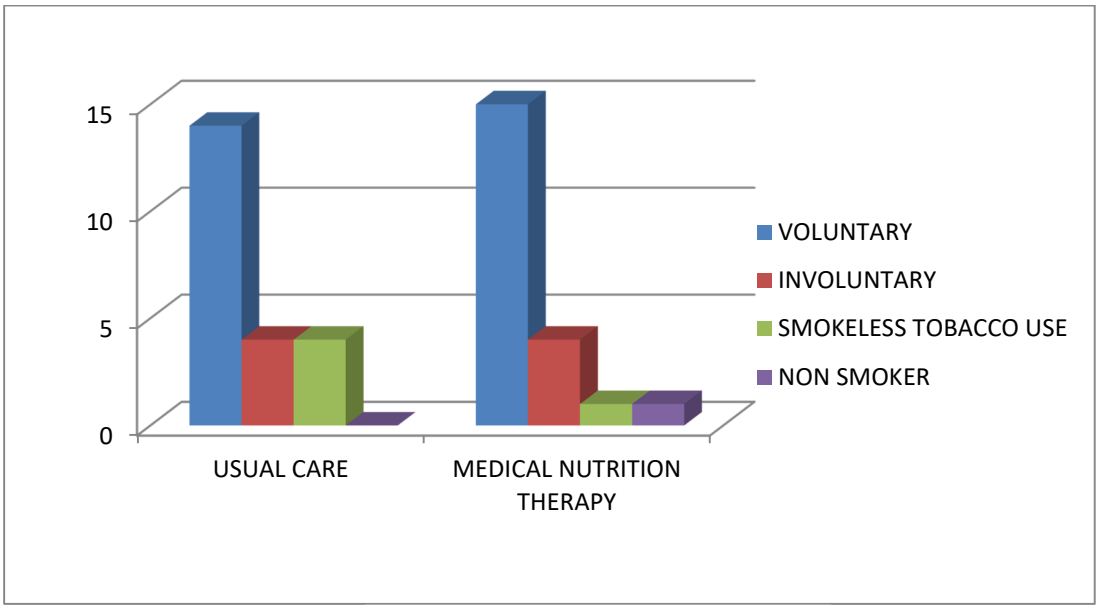
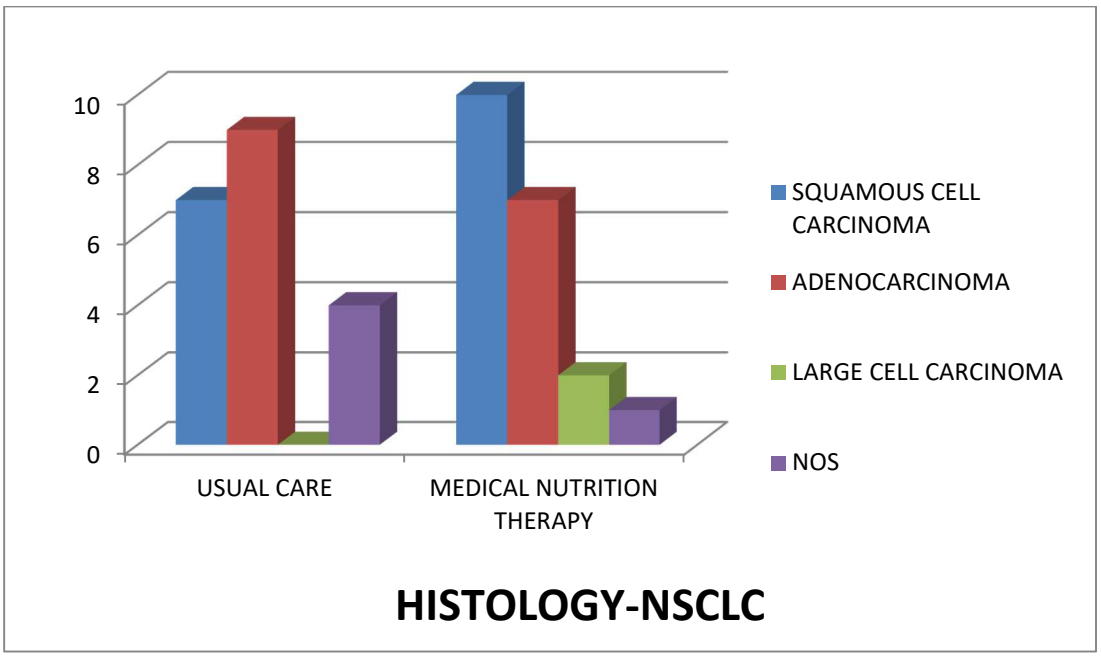
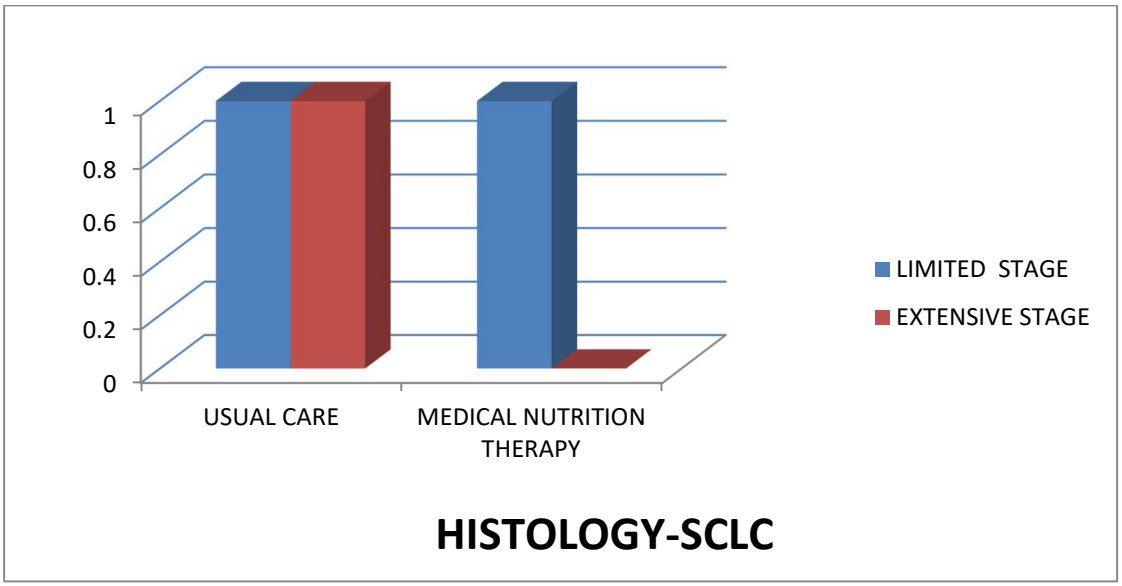


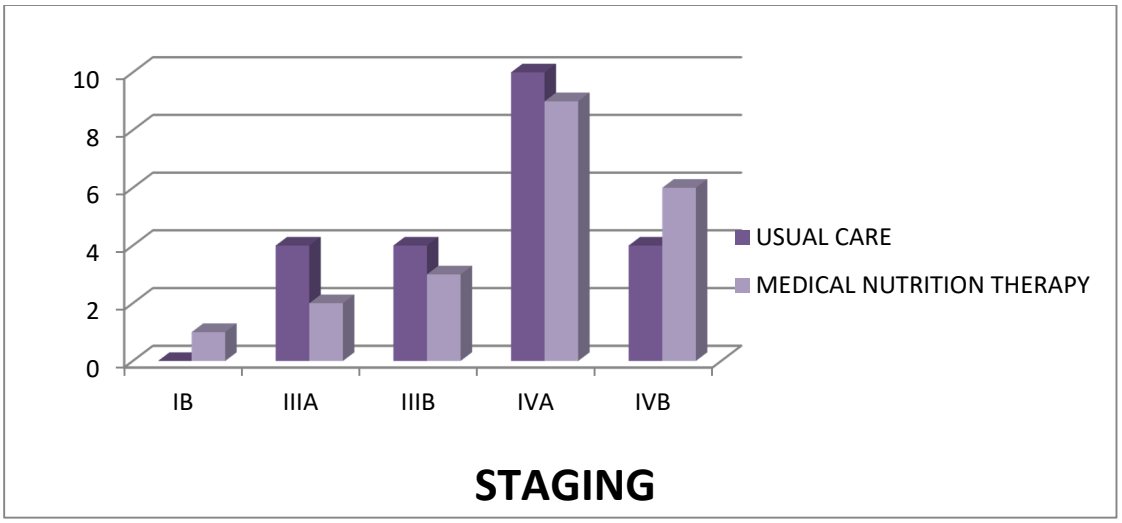
SMOKING PATTERN



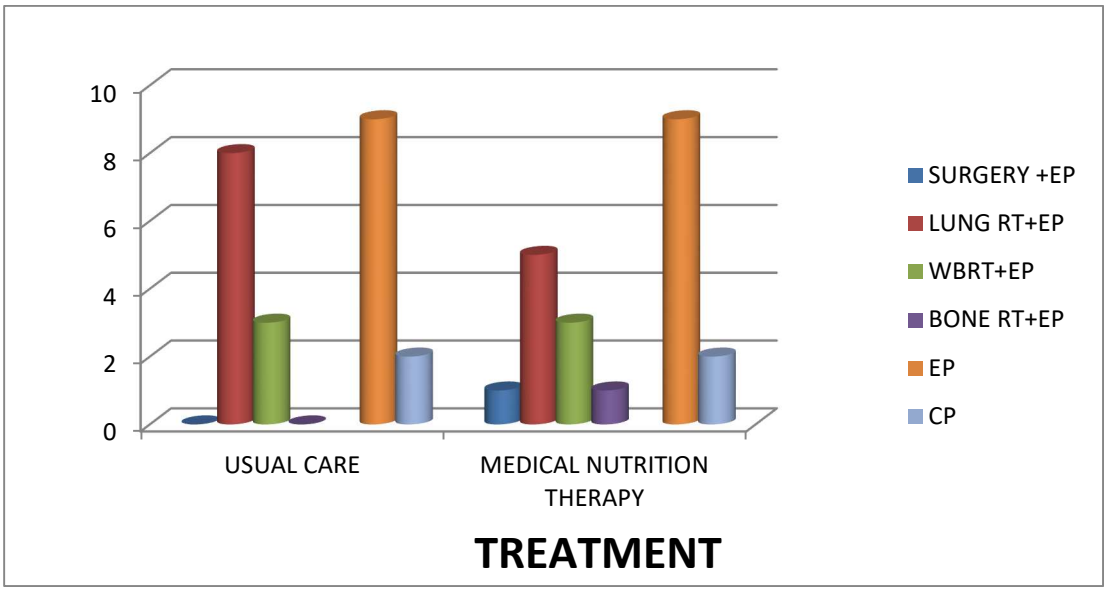
HISTOLOGY-NSCLC



HISTOLOGY-SCLC



STAGING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USUAL CARE
MEDICAL NUTRITION THERAPY
TREATMENT
SURGERY +EP
LUNG RT+EP
WBRT+EP
BONE RT+EP
EP
CP

Table 1: Prevalence of malnutrition for different type of cancer (von Meyenfeldt, 2005)

Tumour site	Prevalence of malnutrition (%)
Pancreas	80 – 85
Stomach	65 – 85
Head and neck	65 – 75
Oesophagus	60 – 80
Lung	45 – 60
Colon/Rectum	30 – 60
Urogical	10
Gynaecological	15

Figure 1: Prevalence of cancer-related symptoms and side-effects (Benjamin HL et al.2008)

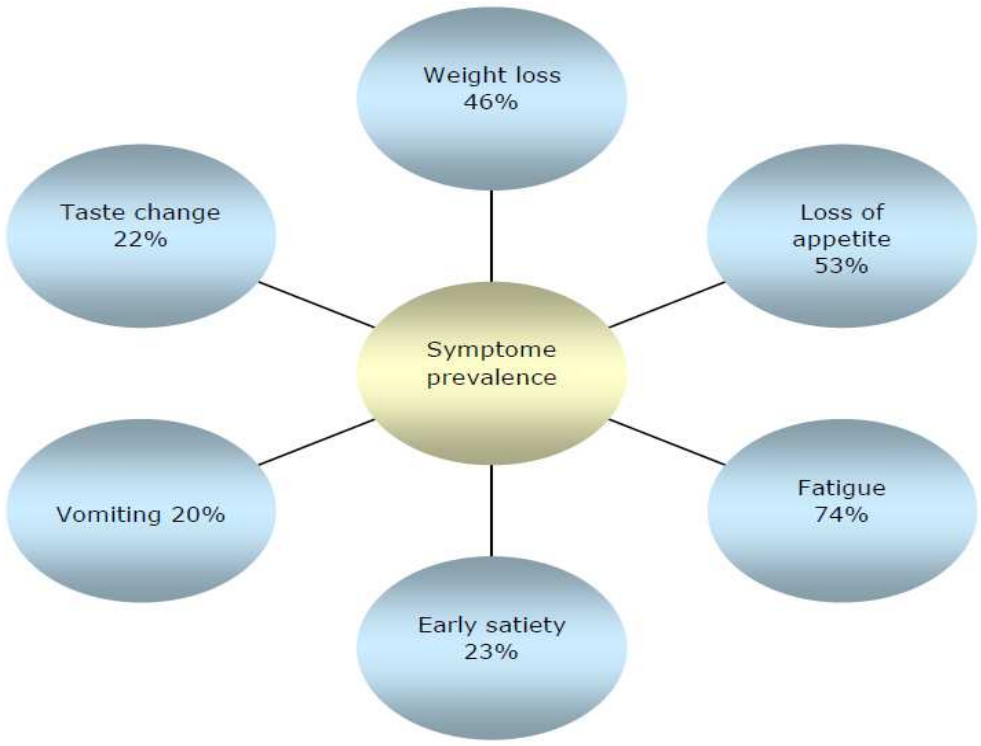


Table 2 : Metabolic alterations in cancer cachexia

Protein	Lipid	Carbohydrate
↑ protein breakdown	↑ fat breakdown	↑ glucose utilization
↑ skeletal muscle protein breakdown	↓ fat synthesis	↑ glucose synthesis
↓ synthesis of skeletal muscle protein	↓ serum lipoprotein lipase activity	Glucose intolerance
↑ synthesis of acute phase proteins	↑ blood lipids	Insulin resistance
↑ urinary nitrogen loss		Hyperinsulinemia

Figure 2: Consequences of cancer-associated malnutrition (Caro MM et al., 2006)

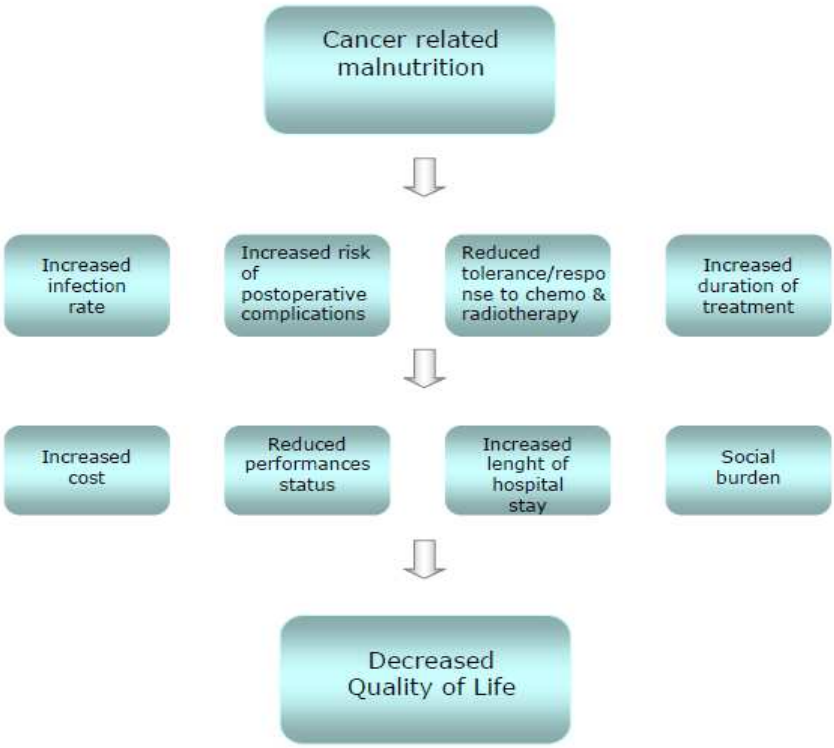


Figure 3: Percent of patients experiencing weight loss (>10%) based on stage of cancer (Ravasco et al. 2004)

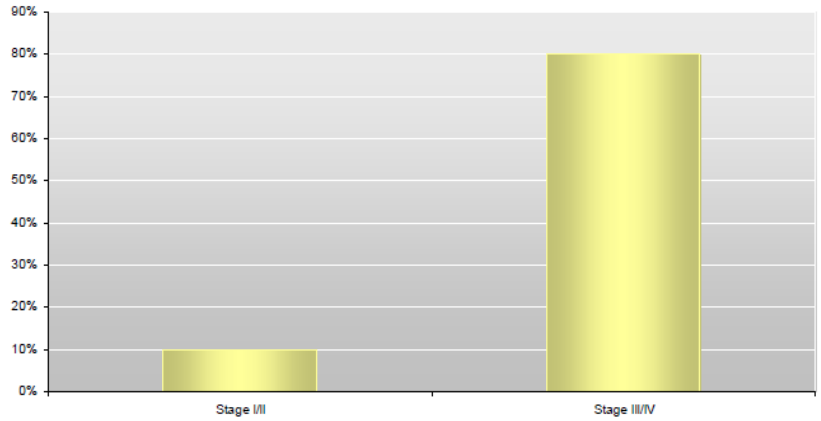


Figure 4: Effect of weight loss on survival (DeWys et al. 1980)

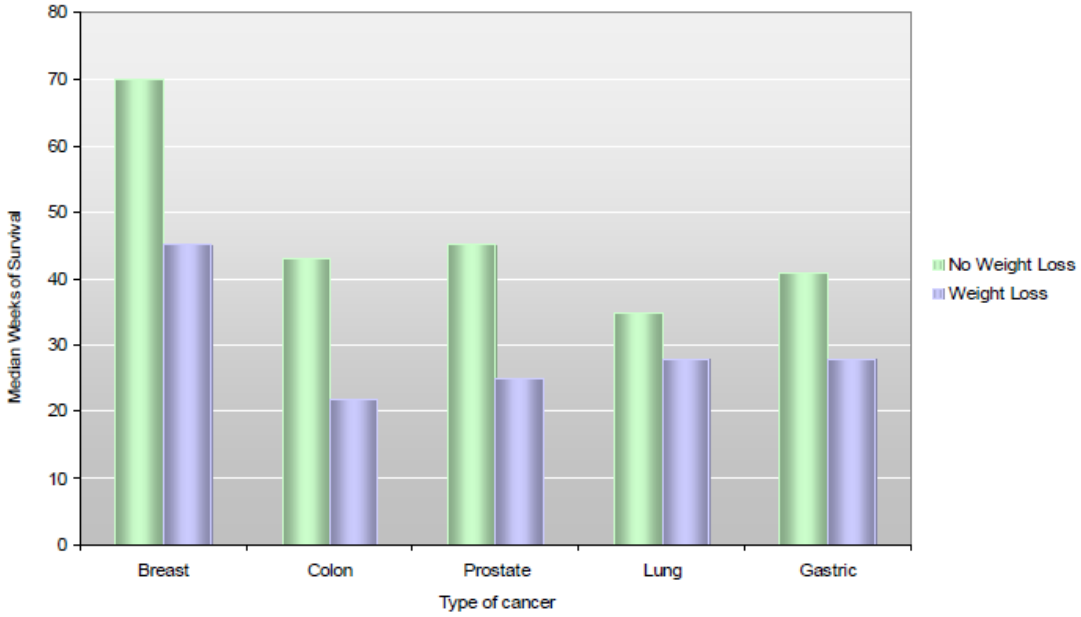


Figure 5: The cachexia journey (Benjamin HL et al. 2008)

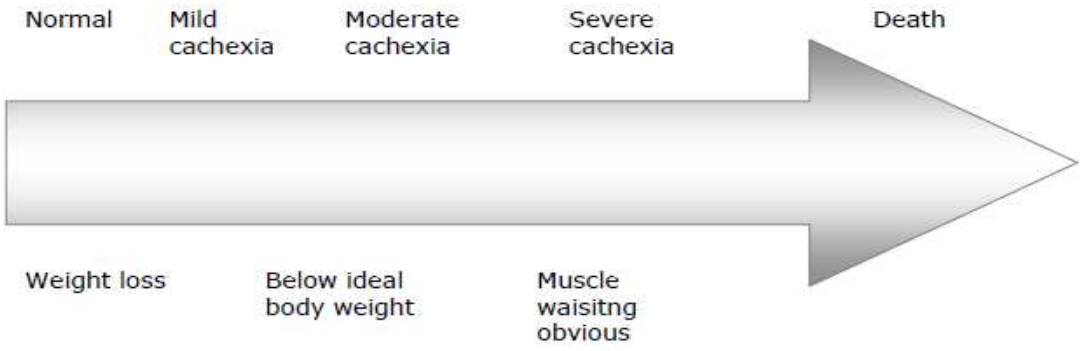


Table 3 : Mediators of cancer cachexia

Pro-Inflammatory and Procachectic Cytokines	Hormones	Tumor-derived Factors
TNF-α	Cortisol	PIF
IL-1	Hyperglucagonemia	LMF
IL-6	Increased insulin resistance	
IFN-γ		
LIF		

Table 4: Factors contributing to cachexia in patients with solid tumor cancer

Tumor			
↓		↓	
Produces tumor derived factors		Causes inflammatory response, which causes	
↓	↓	↓	↓
Lipid Mobilizing Factor	Proteolysis Inducing Factor	Change in hormones regulation	Synthesis of inflammatory cytokines
↓	↓	↓	↓
Promotes breakdown of fats	Promotes muscle breakdown/increases metabolism	Alters glucose metabolism/increases metabolism	Decreases appetite
↓	↓	↓	↓
Loss of fat tissue	Loss of muscle tissue	Decreases muscle glucose utilization	Decreases food intake
↓	↓	↓	↓
Cachexia (Weight Loss/Muscle Wasting)			

Figure 6: Multifactorial causes of cancer cachexia (Van Cutsem E, Arends J, 2005)

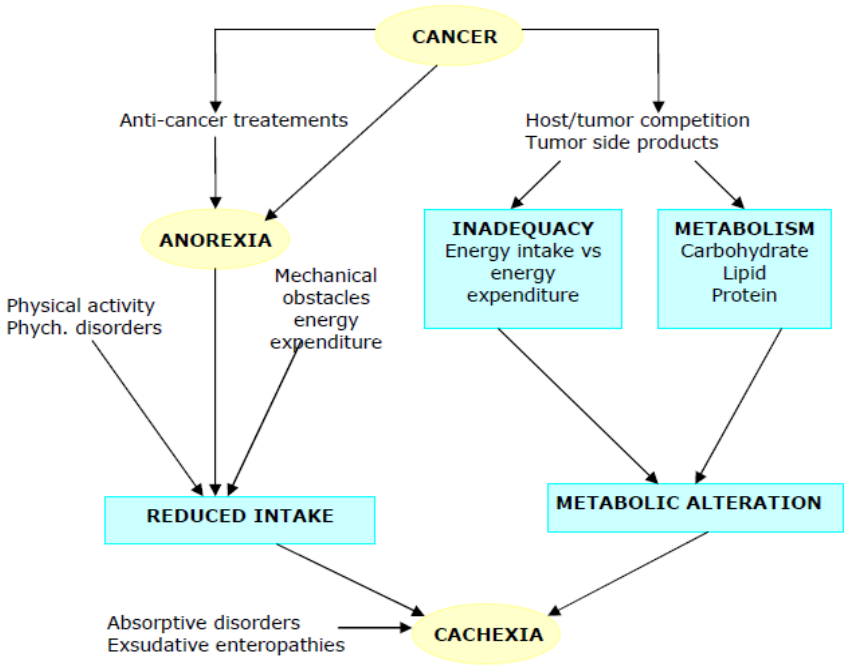


Figure: 7 Integrated nutrition care process in the continuum of cancer

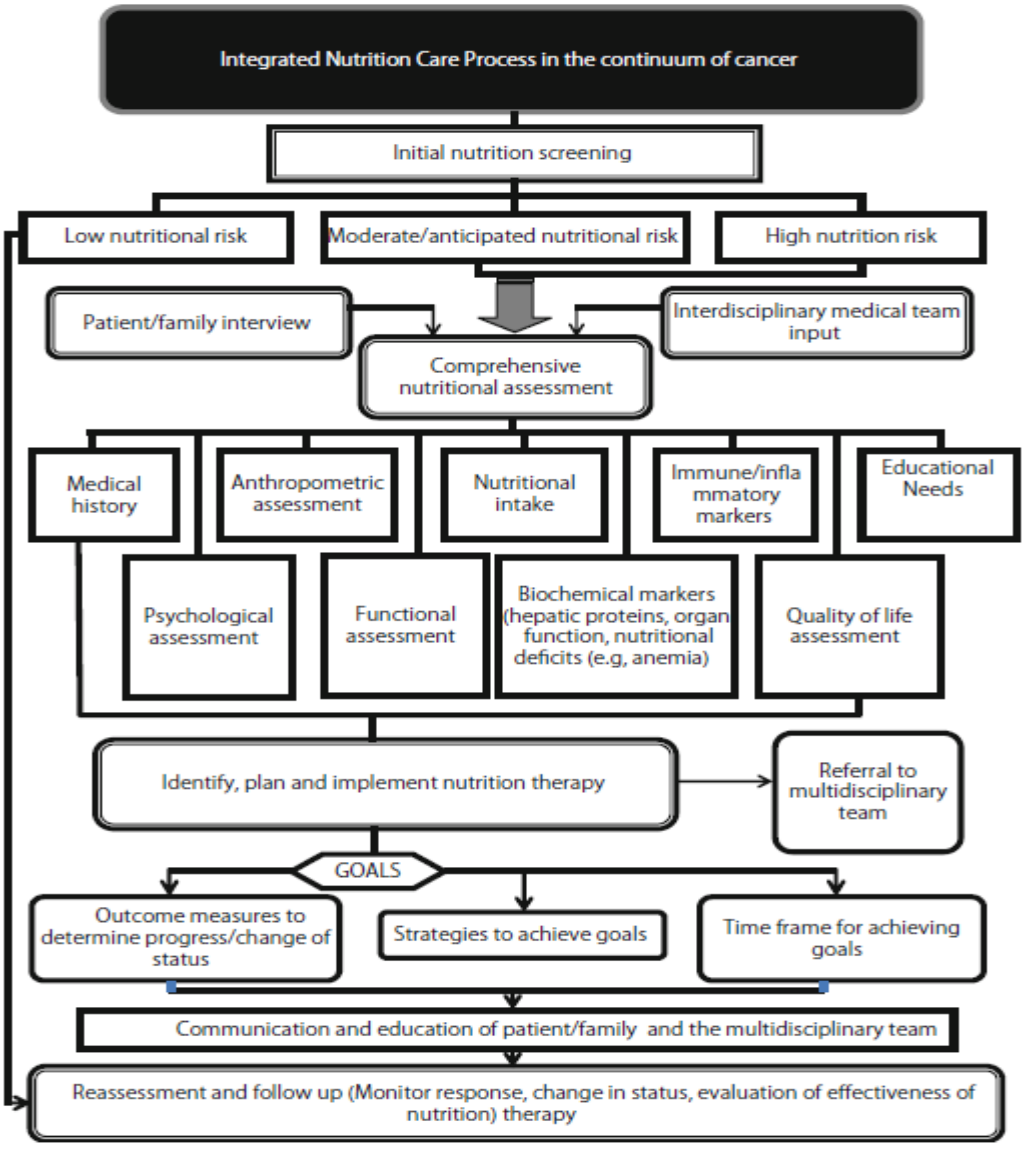


Table 5 Screening tools validated in cancer patients

SL.NO	TOOL	ITEMS	DATA INCLUDED	completed by	REF NO
1.	Malnutrition Screening Tool	3	Weight history, effect of appetite,	Patient.	16
2.	Mini Nutritional Assessment	18	Weight history, food intake ,activity, psychological stress, Anthropometric measurements	Practitioner	18
3.	Patient Generated Subjective Global Assessment	17	Weight history, food intake , activity,symptoms, metabolic demand, physical assessment	Patient and Practitioner	20

Table 6 Strengths and Limitations of Various Dietary Assessment Methods Used in Clinical Settings

Strengths and Limitations of Various Dietary Assessment Methods Used in Clinical Settings			
	Strengths	**Limitations**	**Applications**
24-Hour Recall	Does not require literacy Relatively low respondent burden Data may be directly entered into a dietary analysis program May be conducted in-person or over the telephone	Dependent on respondent's memory Relies on self-reported information Requires skilled staff Time consuming Single recall does not represent usual intake	Appropriate for most people as it does not require literacy Useful for the assessment of intake of a variety of nutrients and assessment of meal patterning and food group intake Useful counseling tool
Food Frequency	Quick, easy and affordable May assess current as well as past diet In a clinical setting, may be useful as a screening tool	Does not provide valid estimates of absolute intake of individuals Can't assess meal patterning May not be appropriate for some population groups	Does not provide valid estimates of absolute intake for individuals, thus of limited usefulness in clinical settings May be useful as a screening tool, however, further development research is needed
Food Record	Does not rely on memory Food portions may be measured at the time of consumption Multiple days of records provide valid measure of intake for most nutrients	Recording foods eaten may influence what is eaten Requires literacy Relies on self-reported information Requires skilled staff Time consuming	Appropriate for literate and motivated population groups Useful for the assessment of intake of a variety of nutrients and assessment of meal patterning and food group intake Useful counseling tool
Diet History	Able to assess usual intake in a single interview Appropriate for most people	Relies on memory Time consuming (1 to 1-1/2 hours) Requires skilled interviewer	Appropriate for most people as it does not require literacy Useful for assessing intake of nutrients, meal patterning and food group intake Useful counseling tool

Table 7 Calculating energy requirements

Basal energy expenditure (BEE)
For females: $55(9.6\times \text{wt in kg})+(1.7\times \text{ht in cm})-(4.7\times \text{age})$
For males: $66.5(13.7\times \text{wt in kg})+(5\times \text{ht in cm})-(6.8\times \text{age})$
For weight maintenance needs: $\text{BEE}\times 1.15-1.3$
For weight anabolism needs: $\text{BEE}\times 1.5$

Table 8 Activity and stress factors for calculating total energy expenditure

Activity level	
Bedrest	1.2
Low activity	1.3
Moderate activity	1.5–1.75
Highly active	2.0
Injury factors:	
Minor surgery	1.1
Major surgery	1.3
Mild infection	1.2
Moderate infection	1.2–1.4
Sepsis	1.4–1.8
Skeletal trauma	1.2–1.4
Skeletal or head trauma (treated with steroids)	1.6–1.8

Table 9. Calculating protein requirements

For calculating protein needs : Divide IBW by 2.2 = kg of IBW
For protein maintenance : Multiply $0.8-1.4\times$ kg of IBW
For protein anabolism : Multiply $1.5\times$ kg of IBW

Fig 8. Insertion and feeding points for nasogastric feeding tubes

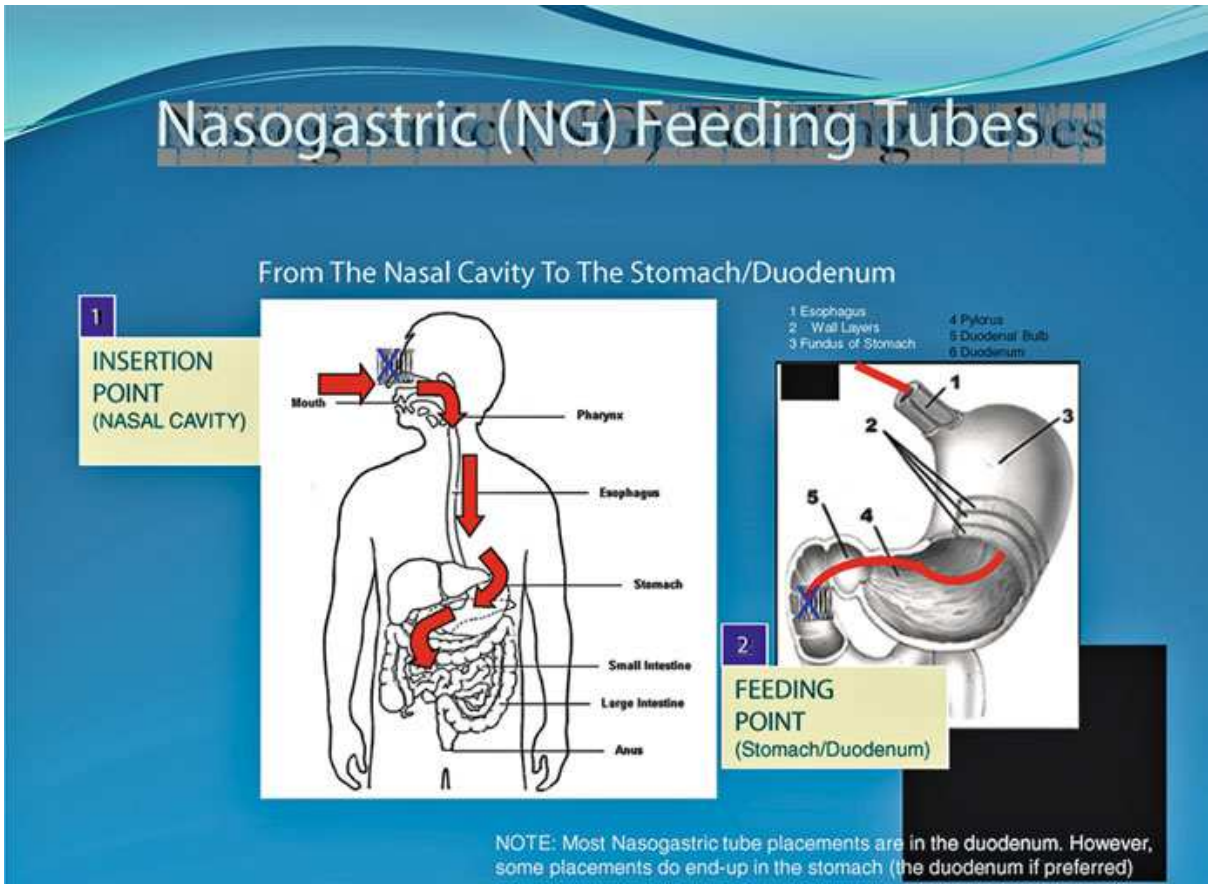


Table 10. General guidelines/criteria for selection of route of feeding.

Criteria for enteral feeding via oral route.	Criteria for enteral feeding via tube feeding	Indications for parenteral nutrition
(a) If the gastrointestinal tract is working- use this. (b) Evaluate risk for dysphagia, aspiration, nausea, vomiting, diarrhea, gastric motility or abdominal pain while eating. (c) Absent above symptoms or if above symptoms are anticipated to resolve in <7 days (d) Consider oral intake.	If patient's condition is not anticipated to resolve in <7 days, consider enteral tube feeding (a) Nutritional intake below 50% of needs (b) Functioning gastrointestinal tract (i) Nasogastric (NG) feeding (insertion point: nasal cavity, feeding point: stomach/duodenum) (ii) Percutaneous endoscopic gastrostomy (PEG): does not require general anesthesia (iii) PEG-J: jejunal extension in patients at risk for aspiration	In patient where enteral feeding is not feasible and the gastrointestinal problems are anticipated to persist – consider parenteral feeding if benefits outweigh other risks: (a) If problems with GI tract function is anticipated (b) Severely malnourished (c) GI problems will persist >7–10 days (d) Nutritional needs not met-(<50%) over 7–10 days (e) Not at risk for sepsis or multiple, resistant infections (f) Unsuccessful enteral feedings (g) Aggressive malignancy and persistent obstruction – functioning GI tract – consider total parenteral nutrition (h) Monitor patient for (i) Serum glucose >300 mg/dL (ii) Serum phosphorous <2 mg/dL (iii) BUN >100 mg/dL (iv) Serum potassium >5.7 or <3.0 mEq/L (v) Catheter-related infection (vi) Malfunction of catheters due to clotted or clogged ports Wean to enteral as soon as patient consumes 50% of calories and protein based on need.

Contraindications for enteral feeding using the gastrointestinal tract	Contraindications for enteral tube feeding using the gastrointestinal tract	Contraindications for parenteral feeding
(a) If patient is hemodynamically unstable (b) Malabsorption (c) Short-bowel syndrome (d) Pseudo obstruction (e) Gastrointestinal fistula (f) Mesenteric ischemia – interruption in blood flow to all or part of the small intestine or the right colon radiation enteritis (g) Paralytic ileus – either by a physical obstruction of the lumen such as a growing tumor, or by a loss of normal peristaltic function	(a) If patient is hemodynamically unstable (b) Malabsorption (c) Short-bowel syndrome (d) Pseudo obstruction (e) Gastrointestinal fistula (f) Mesenteric ischemia – interruption in blood flow to all or part of the small intestine or the right colon radiation enteritis. (g) Paralytic ileus – either by a physical obstruction of the lumen such as a growing tumor, or by a loss of normal peristaltic function	(a) End stage disease (b) Multiple organ failure (c) Sepsis (d) Resistant infections (e) Nutritional support – viewed as a palliative measure (f) The goal is to support hydration (g) Decision must be made based on patients desire. (h) Family preferences should be taken into account. Informed decision based on stage of cancer and prognosis

Fig. 9 Impact of quality of life

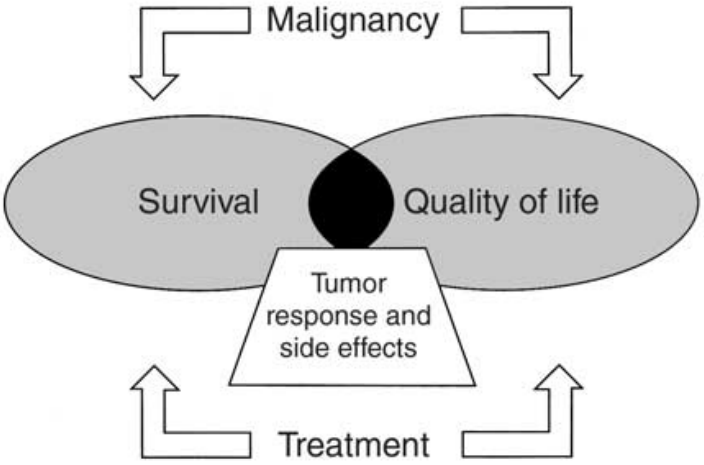


Table 11. Characteristics of the EORTC QLQ-C30 and FACT-G compared

	EORTC QLQ-C30	FACT-G
Number of items	30	27
Response options	Likert scales (4 or 7 options)	Likert scale (5 options)
Recall period	Past week	Past 7 days
Item format	Questions	Statements
Item organisation	Items are not always grouped into scales and never explicitly so. The five physical functioning items are grouped into a Guttman scale and recognisably measure the same construct.	Items are explicitly grouped into scales.
Scaling	• Five 'functioning' scales, measuring: Physical functioning (PF; 5 items) Role functioning (RF; 2 items) Emotional functioning (EF; 4 items) Social functioning (SF; 2 items) Cognitive functioning (CF; 2 items) • One three-item symptom scale measuring fatigue. • Two two-item symptom scales measuring pain and nausea and vomiting. • Six single-item symptom scales measuring dyspnoea, insomnia, appetite loss, constipation, diarrhoea and financial impact. • Overall global health status/QoL scale (2 items)	• Four 'well-being' subscales, measuring – Physical well-being (PWB; 7 items) Social/family well-being (SWB; 7 items) Emotional well-being (EWB; 6 items) Functional well-being (FWB; 7 items, including global QoL item) • Overall FACT-G score (total of all 27 items)
Time to administer	11 min	5–10 min
Administration[a]	Self, interviewer, computer	Self, interviewer, computer
Language versions	79	53

STATISTIC OF USUAL CARE GROUP

1. WEIGHT [WT]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	WTC	47.4682	22	7.82349	1.66797
	WT2C	48.0636	22	8.43138	1.79758

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	WTC & WT2C	22	.960	.000

2. LEAN BODY MASS[LBW]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	LBWC	39.8286	22	5.73265	1.22221
	LBW2C	40.1505	22	6.03236	1.28610

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	LBWC & LBW2C	22	.973	.000

3. MID ARM MUSCLE CIRCUMFERENCE[MAMC]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	MAMCC	20.5814	22	3.43833	.73305
	MAMC2C	20.4709	22	3.26178	.69541

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	MAMCC & MAMC2C	22	.952	.000

4. APPETITE

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	APPETITEC	6.0909	22	1.63034	.34759
	APPETITE2C	6.8182	22	1.09702	.23389

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	APPETITEC & APPETITE2C	22	.702	.000

5. PATIENT GENERATED SUBJECTIVE GLOBAL ASSESSMENT[PGSGA]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	PGSGAC	12.9545	22	2.75123	.58656
	PGSGA2C	9.8636	22	1.88466	.40181

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	PGSGAC & PGSGA2C	22	.752	.000

6. ENERGY INTAKE [E]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	EC	1.7198E3	22	675.79843	144.08071
	E2C	1.8594E3	22	700.92053	149.43676

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	EC & E2C	22	.965	.000

7. PROTEIN INTAKE

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	PC	33.8864	22	12.00985	2.56051
	P2C	36.8636	22	12.13533	2.58726

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	PC & P2C	22	.910	.000

8. QOL – FACTG

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	FACT_GC	61.0864	22	12.56243	2.67832
	FACTG2C	68.8136	22	16.33904	3.48349

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	FACT_GC & FACTG2C	22	.646	.001

9. PHYSICAL WELL BEING[PWB]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	PWBC	15.8182	22	4.08990	.87197
	PWB2C	17.7273	22	4.22218	.90017

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	PWBC & PWB2C	22	.571	.006

10. FUNCTIONAL WELL BEING[FWB]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	FWBC	12.6091	22	4.16355	.88767
	FWB2C	15.1364	22	4.22347	.90045

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	FWBC & FWB2C	22	.555	.007

11. C-REACTIVE PROTEIN[CRP]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	CRPC	16.2682	22	5.10680	1.08877
	CRP2C	14.0664	22	4.83996	1.03188

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	CRPC & CRP2C	22	.247	.267

12. PREALBUMIN[PAB]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	PABC	65.0341	22	79.15999	16.87697
	PAB2Cs	44.7814	22	45.36709	9.67230

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	PABC & PAB2Cs	22	.056	.804

STATISTIC OF MEDICAL NUTRIONAL THERAPY GROUP

1. WEIGHT [WT]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	WT	46.8333	21	9.37013	2.04473
	WT2	48.2190	21	8.32164	1.81593

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	WT & WT2	21	.964	.000

2. LEAN BODY MASS[LBW]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	LBW	39.5405	21	7.03800	1.53582
	LBW2	40.3857	21	6.29996	1.37476

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	LBW & LBW2	21	.978	.000

3.MID ARM MUSCLE CIRCUMFERENCE[MAMC]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	MAMC	20.2038	21	3.06351	.66851
	MAMC2	20.5357	21	2.83984	.61970

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	MAMC & MAMC2	21	.960	.000

4.APPETITE

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	APPETITE	6.1905	21	1.40068	.30565
	APPETITE2	6.8571	21	1.01419	.22131

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	APPETITE & APPETITE2	21	.548	.010

5. PATIENT GENERATED SUBJECTIVE GLOBAL ASSESSMENT[PGSGA]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	PGSGA	13.1905	21	2.74989	.60008
	PGSGA2	9.6190	21	1.62715	.35507

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	PGSGA & PGSGA2	21	.743	.000

6. ENERGY INTAKE[E]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	ENERGY	1.5400E3	21	386.13145	84.26079
	E2	2.0607E3	21	322.90976	70.46469

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	ENERGY & E2	21	.989	.000

7. PROTEIN INTAKE

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	PROTEIN	33.8810	21	10.40421	2.27039
	P2	66.0952	21	8.22134	1.79404

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	PROTEIN & P2	21	.941	.000

8. QOL – FACTG

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	FACTG	58.9762	21	15.48312	3.37869
	FACTG2	69.8190	21	11.60054	2.53145

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	FACTG & FACTG2	21	.615	.003

9. PHYSICAL WELL BEING[PWB]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	PWB	14.8095	21	4.33150	.94521
	PWB2	18.9048	21	3.19225	.69661

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	PWB & PWB2	21	.552	.009

10. FUNCTIONAL WELL BEING[FWB]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	FWB	11.0476	21	5.25810	1.14741
	FWB2	14.2381	21	3.04803	.66513

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	FWB & FWB2	21	.080	.729

11. C-REACTIVE PROTEIN[CRP]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	CRP	16.5552	21	4.41697	.96386
	CRP2	13.0486	21	3.69715	.80678

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	CRP & CRP2	21	.580	.006

12.

12.PREALBUMIN[PAB]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	PAB	49.0552	21	55.12013	12.02820
	PAB2	58.2190	21	46.39713	10.12468

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	PAB & PAB2	21	.407	.067

COMPARISON OF USUAL CARE AND MEDICAL NUTRITIONAL THERAPY GROUPS

1. WEIGHT [WT]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	wdc	.9095	21	1.90497	.41570
	WD	1.3857	21	2.57959	.56291

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	wdc & WD	21	-.177	.444

2. LEAN BODY MASS[LBW]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	lbwdc	.5162	21	1.07934	.23553
	LBD	.8452	21	1.58316	.34547

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	lbwdc & LBD	21	-.141	.542

3.MID ARM MUSCLE CIRCUMFERENCE[MAMC]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	mamcdc	-.0205	21	.98875	.21576
	MAMD	.3319	21	.86618	.18902

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	mamcdc & MAMD	21	-.123	.594

4. APPETITE

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	adc	.8571	21	1.01419	.22131
	AD	.6667	21	1.19722	.26125

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	adc & AD	21	.124	.594

5. PATIENT GENERATED SUBJECTIVE GLOBAL ASSESSMENT[PGSGA]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	pgsadc	3.2857	21	1.61688	.35283
	PSAD	3.5714	21	1.88604	.41157

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	pgsadc & PSAD	21	-.237	.302

6. ENERGY INTAKE[E]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	edc	1.6271E2	21	153.41354	33.47758
	ED	5.2071E2	21	81.88843	17.86952

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	edc & ED	21	-.114	.622

7. PROTEIN INTAKE

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	pdc	3.4048	21	4.84154	1.05651
	PD	32.2143	21	3.84893	.83991

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	pdc & PD	21	.090	.697

8. QOL – FACTG

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	factdc	8.4286	21	12.49609	2.72687
	FACD	10.8429	21	12.38259	2.70210

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	factdc & FACD	21	-.257	.260

9. PHYSICAL WELL BEING[PWB]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	pwdc	2.2381	21	3.61808	.78953
	PWD	4.0952	21	3.70006	.80742

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	pwdc & PWD	21	-.293	.197

10. FUNCTIONAL WELL BEING[FWB]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	FWD	3.1905	21	5.86190	1.27917
	fwdc	2.6476	21	4.01492	.87613

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	FWD & fwdc	21	-.230	.315

11. C-REACTIVE PROTEIN[CRP]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	crpdc	-2.1657	21	6.25380	1.36469
	CRPD	-3.5067	21	3.77096	.82289

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	crpdc & CRPD	21	-.247	.280

12. PREALBUMIN[PAB]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	padc	-20.8029	21	91.15700	19.89209
	PAD	9.1638	21	55.77787	12.17173

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	padc & PAD	21	-.018	.939

APPENDIX

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI -3

Telephone No : 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To

Dr.P.N.Sathiyamoorthy,
III Year, DM(Oncology) Post Graduate,
Madras Medical College, Chennai -3

Dear Dr.P.N.Sathiyamoorthy,

The Institutional Ethics committee of Madras Medical College, reviewed and discussed your application for approval of the proposal entitled "Nutritional assessment and intervention in lung cancer patients undergoing treatment" No.07122012.

The following members of Ethics Committee were present in the meeting held on 11.12.2012 conducted at Madras Medical College, Chennai -3.

1. Dr.S.K.Rajan, M.D.FRCP, DSc --- Chairperson
2. Prof. R. Nandhini MD -- Member Secretary
   Director, Instt. of Pharmacology ,MMC, Ch-3
3. Prof. Dr.A.Radhakrishnan MD -- Member
   Director , Inst. Of Internal Medicine, MMC, Ch-3
4. Prof. Meenalochani, MD -- Member
   Director , Instt. of O& G, Chennai
5. Prof. Shyamraj MD -- Member
   Director i/c , Instt. of Biochemistry , MMC, Ch-3
6. Prof. P. Karkuzhali. MD -- Member
   Prof., Instt. of Pathology, MMC, Ch-3
7. Prof. S.Devivanayagam MS -- Member
   Prof of Surgery, MMC, Ch-3
8. Thiru. S. Govindsamy. BA, BL -- Lawyer
9. Tmt.Arnold Saulina MA MSW --- Social Scientist

We approve the proposal to be conducted in its presented form.

Sd/ Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, and SAE occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

R Nandini 21/12/12
Member Secretary, Ethics Committee

ஆராய்ச்சி தகவல் தாள்

சென்னை மருத்துவக் கல்லூரி மற்றும் இராஜீவ் காந்தி அரசு பொது மருத்துவமனையில் உள்ள புற்றுநோய் மருத்துவ சிகிச்சை பிரிவுக்கு வரும் நுரையீரல் புற்றுநோயாளிகள் பற்றிய ஒரு ஆராய்ச்சி இங்கு நடைபெற்று வருகிறது.

நுரையீரல் புற்றுநோய் பாதிக்கப்பட்ட பலர் பல்வேறு காரணங்களால் சரியான உணவு முறையை எடுத்துக் கொள்ள முடிவதில்லை. அதனால் அவர்கள் உடல் எடை குறைந்து மெலிந்து விடுகின்றனர். அவர்களுக்கு தகுந்த உணவு முறை ஆலோசனைகளையும், அதிக சத்து மற்றும் புரதம் மிகுந்த உணவுகளை உட்கொண்டால் நல்ல ஆரோக்கியத்துடன் இருந்து புற்றுநோய் சிகிச்சையும் தொடர்ந்து மேற்கொள்ள முடியும்.

நீங்களும் இந்த ஆராய்ச்சியில் பங்கேற்க விரும்புகிறோம். அதனால் தங்களது நோயின் ஆய்வறிக்கைக்கோ அல்லது சிகிச்சைக்கோ பாதிப்பு ஏற்படாது என்பதை தெரிவித்துக் கொள்கிறோம். இந்த ஆராய்ச்சியில் உங்களுடைய இரத்த மாதிரியை எடுத்து சில சிறப்பு பரிசோதனைக்கு உட்படுத்தி அதன் தகவல்களை ஆராய்வோம்.

முடிவுகளை அல்லது கருத்துக்களை வெளியிடும் போதோ அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிட மாட்டோம் என்பதையும் உறுதியளிக்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய முழு விருப்பத்தை சார்ந்தது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியிலிருந்து பின் வாங்கலாம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த சிறப்புப் பரிசோதனைகளின் முடிவுகளை ஆராய்ச்சியின் போது அல்லது ஆராய்ச்சியின் முடிவின்போது தங்களுக்கு அறிவிக்கப்படும் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம்

பங்கேற்பாளர் கையொப்பம்

தேதி :

ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராய்ச்சி தலைப்பு : நுரையீரல் புற்றுநோய் உள்ளவர்களுக்கான உணவு முறையை அளவீடு செய்தலும் மற்றும் உணவு முறையை மாற்றம் செய்தலும்.

பெயர் :
வயது :
பால் :
முகவரி :

தேதி :
உள் நோயாளி பிரிவு எண் :
ஆராய்ச்சி சேர்க்கை எண் :
தகவல் தொடர்பு எண் :

இந்த ஆராய்ச்சில் விவரங்களும் அதன் நோக்கங்களும் முழுமையாகவும் தெளிவாகவும் எனக்கு விளக்கப்பட்டது.

எனக்கு விளக்கப்பட்ட விவரங்களை புரிந்துக் கொண்டு நான் எனது சம்மதத்தை தெரிவிக்கின்றேன்.

எனக்கு இந்த ஆராய்ச்சியில் இரத்தப் பரிசோதனை மூலம் சி-ரியாக்டிவ் புரோட்டின் மற்றும் ப்ரி-ஆல்புமின் ஆகிய புரதங்களின் அளவை இருமுறை பரிசோதனை செய்துகொள்ள சம்மதம்.

ஆராய்ச்சியாளர் அறிவுறுத்தும் உணவு முறை ஆலோசனைகளாகிய அதிக சத்து மற்றும் புரதம் மிகுந்த உணவுகளை முறைப்படி உட்கொள்ள சம்மதிக்கிறேன்.

இவர்கள் கூறும் கட்டுப்பாடுகளை கடை பிடிக்கவும், மற்றும் ஆராய்ச்சி முடியும் வரை தொடர்ந்து ஒத்துழைப்பு அளிக்கவும் சம்மதம்.

இந்த ஆராய்ச்சி, பிறரின் நிர்பந்தமின்றி என் சொந்த விருப்பத்தின் பேரில் பங்குகொள்கிறேன் மற்றும் இந்த ஆராய்ச்சியிலிருந்து எந்நேரமும் விலகிக்கொள்ளலாம் என்பதையும் அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையும் நான் புரிந்து கொண்டேன்.

இந்த உணவு முறை பற்றிய ஆராய்ச்சியின் விவரங்கள் கொண்ட தாளை பெற்றுக்கொண்டேன்.

நான் என்னுடைய சுயநினைவுடனும், முழு சுதந்திரத்துடனும் இந்த மருத்துவ ஆராய்ச்சியில் பங்குகொள்ள சம்மதிக்கிறேன்.

கையொப்பம்.

PROFORMA

NUTRITIONAL ASSESSMENT AND INTERVENTION IN LUNG CANCER PATIENTS UNDERGOING TREATMENT

NAME: **AGE:** **SEX:** **MO.NO:**
STUDY NO:

ADDRESS &CONTACT NO:

HT: **WT:** **BMI:** **LBM:** **%OF WT LOSS:**

MAC: **TST:** **MAMC:**

APPETITE (VAS):

ECOG PS:

SCORED PG- SGA:

SITE OF PRIMARY TUMOR:

HISTOLOGY & STAGE:

TREATMENT DETAILS:

COMORBIDITY:

DATE OF ENROLLMENT:

DATE OF REASSESSMENT: 1. **2.**

DATE OF BLOOD SAMPLE COLLECTION: 1. **2.**

Scored Patient-Generated Subjective Global Assessment (PG-SGA)

Patient ID Information

History (Boxes 1-4 are designed to be completed by the patient.)

1. Weight *(See Worksheet 1)*

In summary of my current and recent weight:

I currently weigh about _____ kg
I am about _____ cm tall

One month ago I weighed about _____ kg
Six months ago I weighed about _____ kg

During the past two weeks my weight has:
☐ decreased (1) ☐ not changed (0) ☐ increased (0)

Box 1 ☐

2. Food Intake: As compared to my normal intake, I would rate my food intake during the past month as:
☐ unchanged (0)
☐ more than usual (0)
☐ less than usual (1)
I am now taking:
☐ *normal food* but less than normal amount (1)
☐ little solid food (2)
☐ only liquids (3)
☐ only nutritonal supplements (3)
☐ very little of anything (4)
☐ only tube feedings or only nutrition by vein (0)

Box 2 ☐

3. Symptoms: I have had the following problems that have kept me from eating enough during the past two weeks (check all that apply):
☐ no problems eating (0)
☐ no appetite, just did not feel like eating (3)
☐ nausea (1)
☐ constipation (1)
☐ mouth sores (2)
☐ things taste funny or have no taste (1)
☐ problems swallowing (2)
☐ pain; where? (3)_____
☐ other** (1) _____
☐ vomiting (3)
☐ diarrhea (3)
☐ dry mouth (1)
☐ smells bother me (1)
☐ feel full quickly (1)

** Examples: depression, money, or dental problems

Box 3 ☐

4. Activities and Function: Over the past month, I would generally rate my activity as:
☐ normal with no limitations (0)
☐ not my normal self, but able to be up and about with fairly normal activities (1)
☐ not feeling up to most things, but in bed or chair less than half the day (2)
☐ able to do little activity and spend most of the day in bed or chair (3)
☐ pretty much bedridden, rarely out of bed (3)

Box 4 ☐

Additive Score of the Boxes 1-4 ☐ **A**

The remainder of this form will be completed by your doctor, nurse, or therapist. Thank you.

5. Disease and its relation to nutritional requirements *(See Worksheet 2)*

All relevant diagnoses (specify) _____

Primary disease stage (circle if known or appropriate) I II III IV Other _____

Age _____

Numerical score from Worksheet 2 ☐ **B**

6. Metabolic Demand *(See Worksheet 3)*

Numerical score from Worksheet 3 ☐ **C**

7. Physical *(See Worksheet 4)*

Numerical score from Worksheet 4 ☐ **D**

Global Assessment *(See Worksheet 5)*
☐ Well-nourished or anabolic (SGA-A)
☐ Moderate or suspected malnutrition (SGA-B)
☐ Severely malnourished (SGA-C)

Total PG-SGA score
(Total numerical score of A+B+C+D above) ☐
(See triage recommendations below)

Clinician Signature _____ RD RN PA MD DO Other __ Date _____

Nutritional Triage Recommendations: Additive score is used to define specific nutritional interventions including patient & family education, symptom management including pharmacologic intervention, and appropriate nutrient intervention (food, nutritional supplements, enteral, or parenteral triage). First line nutrition intervention includes optimal symptom management.

0-1 No intervention required at this time. Re-assessment on routine and regular basis during treatment.
2-3 Patient & family education by dietitian, nurse, or other clinician with pharmacologic intervention as indicated by symptom survey (Box 3) and laboratory values as appropriate.
4-8 Requires intervention by dietitian, in conjunction with nurse or physician as indicated by symptoms survey (Box 3).
≥ 9 Indicates a critical need for improved symptom management and/or nutrient intervention options.

Worksheets for PG-SGA Scoring

Boxes 1-4 of the PG-SGA are designed to be completed by the patient. The PG-SGA numerical score is determined using 1) the parenthetical points noted in boxes 1-4 and 2) the worksheets below for items not marked with parenthetical points. Scores for boxes 1 and 3 are additive within each box and scores for boxes 2 and 4 are based on the highest scored item checked off by the patient.

Worksheet 1 - Scoring Weight (Wt) Loss

To determine score, use 1 month weight data if available. Use 6 month data only if there is no 1 month weight data. Use points below to score weight change and add one extra point if patient has lost weight during the past 2 weeks. Enter total point score in Box 1 of the PG-SGA.

Wt loss in 1 month	Points	Wt loss in 6 months
10% or greater	4	20% or greater
5-9.9%	3	10 -19.9%
3-4.9%	2	6 - 9.9%
2-2.9%	1	2 - 5.9%
0-1.9%	0	0 - 1.9%

Score for Worksheet 1 ☐
Record in Box 1

Worksheet 2 - Scoring Criteria for Condition

Score is derived by adding 1 point for each of the conditions listed below that pertain to the patient.

Category	Points
Cancer	1
AIDS	1
Pulmonary or cardiac cachexia	1
Presence of decubitus, open wound, or fistula	1
Presence of trauma	1
Age greater than 65 years	1

Score for Worksheet 2 = ☐
Record in Box B

Worksheet 3 - Scoring Metabolic Stress

Score for metabolic stress is determined by a number of variables known to increase protein & calorie needs. The score is additive so that a patient who has a fever of > 102 degrees (3 points) and is on 10 mg of prednisone chronically (2 points) would have an additive score for this section of 5 points.

Stress	none (0)	low (1)	moderate (2)	high (3)
Fever	no fever	>99 and <101	≥101 and <102	≥102
Fever duration	no fever	<72 hrs	72 hrs	> 72 hrs
Steroids	no steroids	low dose (<10mg prednisone equivalents/day)	moderate dose (≥10 and <30mg prednisone equivalents/day)	high dose steroids (≥30mg prednisone equivalents/day)

Score for Worksheet 3 = ☐
Record in Box C

Worksheet 4 - Physical Examination

Physical exam includes a subjective evaluation of 3 aspects of body composition: fat, muscle, & fluid status. Since this is subjective, each aspect of the exam is rated for degree of deficit. Muscle deficit impacts point score more than fat deficit. Definition of categories: 0 = no deficit, 1+ = mild deficit, 2+ = moderate deficit, 3+ = severe deficit. Rating of deficit in these categories are *not* additive but are used to clinically assess the degree of deficit (or presence of excess fluid).

Fat Stores:				
orbital fat pads	0	1+	2+	3+
triceps skin fold	0	1+	2+	3+
fat overlying lower ribs	0	1+	2+	3+
Global fat deficit rating	**0**	**1+**	**2+**	**3+**

Muscle Status:				
temples (temporalis muscle)	0	1+	2+	3+
clavicles (pectoralis & deltoids)	0	1+	2+	3+
shoulders (deltoids)	0	1+	2+	3+
interosseous muscles	0	1+	2+	3+
scapula (latissimus dorsi, trapezius, deltoids)	0	1+	2+	3+
thigh (quadriceps)	0	1+	2+	3+
calf (gastrocnemius)	0	1+	2+	3+
Global muscle status rating	**0**	**1+**	**2+**	**3+**

Fluid Status:				
ankle edema	0	1+	2+	3+
sacral edema	0	1+	2+	3+
ascites	0	1+	2+	3+
Global fluid status rating	**0**	**1+**	**2+**	**3+**

Point score for the physical exam is determined by the overall subjective rating of total body deficit.

No deficit	score = 0 points
Mild deficit	score = 1 point
Moderate deficit	score = 2 points
Severe deficit	score = 3 points

Score for Worksheet 4 = ☐
Record in Box D

Worksheet 5 - PG-SGA Global Assessment Categories

	Stage A	Stage B	Stage C
Category	Well-nourished	Moderately malnourished or suspected malnutrition	Severely malnourished
Weight	No wt loss **OR** Recent non-fluid wt gain	~5% wt loss within 1 month (or 10% in 6 months) **OR** No wt stabilization or wt gain (i.e., continued wt loss)	> 5% wt loss in 1 month (or >10% in 6 months) **OR** No wt stabilization or wt gain (i.e., continued wt loss)
Nutrient Intake	No deficit **OR** Significant recent improvement	Definite decrease in intake	Severe deficit in intake
Nutrition Impact Symptoms	None **OR** Significant recent improvement allowing adequate intake	Presence of nutrition impact symptoms (Box 3 of PG-SGA)	Presence of nutrition impact symptoms (Box 3 of PG-SGA)
Functioning	No deficit **OR** Significant recent improvement	Moderate functional deficit **OR** Recent deterioration	Severe functional deficit **OR** recent significant deterioration
Physical Exam	No deficit **OR** Chronic deficit but with recent clinical improvement	Evidence of mild to moderate loss of SQ fat &/or muscle mass &/or muscle tone on palpation	Obvious signs of malnutrition (e.g., severe loss of SQ tissues, possible edema)

Global PG-SGA rating (A, B, or C) = ☐

24 Hour Food Recall

NAME_____ DATE _____

AGE_____

"I would like to know what you've eaten within the past 24 hours. Please tell me everything you ate or drank, including meals, snacks, beverages, candy and alcohol? Why don't you start with the last thing you've had to eat or drink today and we'll go backwards."

				Dairy Products	Meat or Substitute	Fruits	Vegetables	Grains	Fats, Oils, Sweets
Time	Place	Food or Beverage	Amount	This Side For Office Use					
Recommended servings/day for adolescents				3-4	3	2-4	3-5	6-11	2
Is this a typical day?_____									
Total Number of Servings									

Nutrients diet may be lacking in:_____

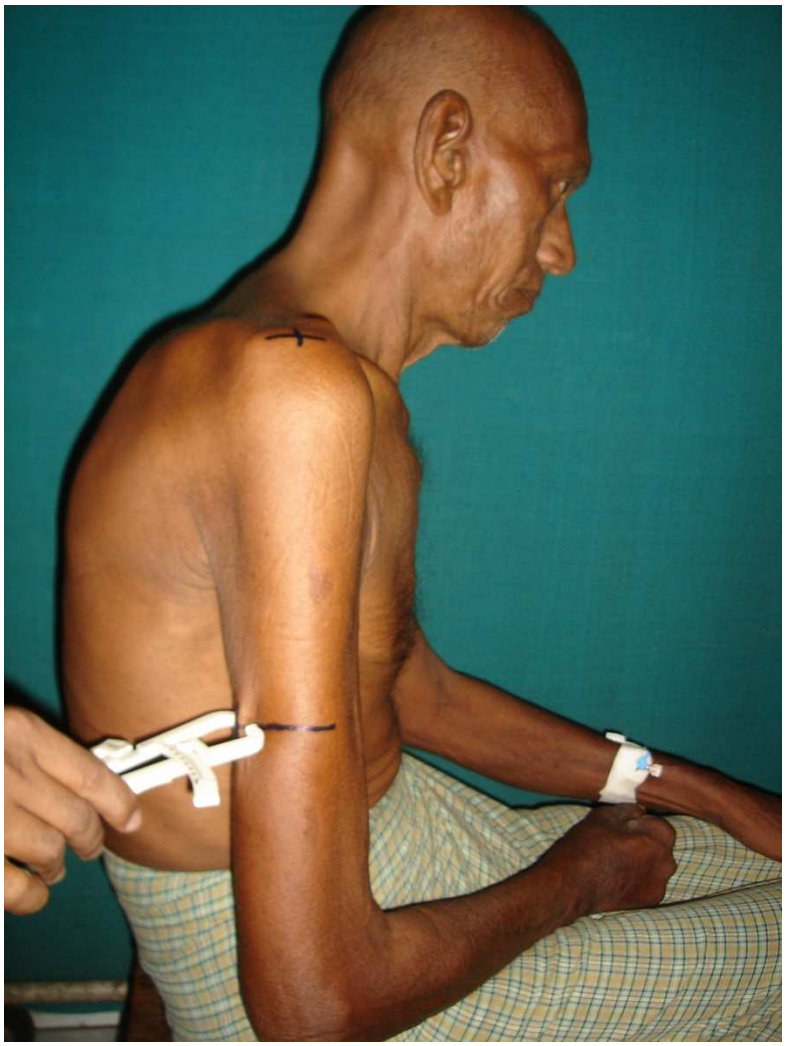
Nutrients diet may be excessive in:_____

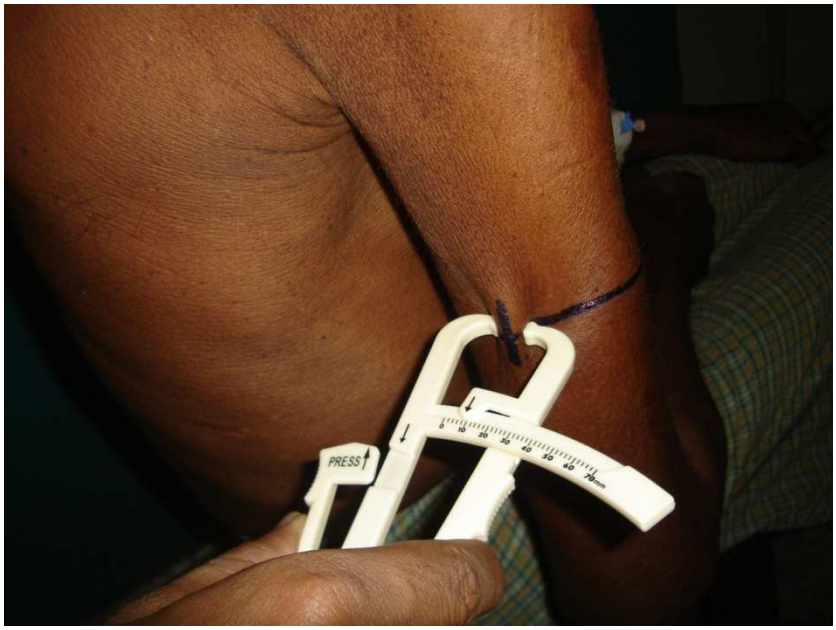
Adapted from Story M, Stang J. eds. Nutrition and the pregnant adolescent: a practical reference guide. Minneapolis, MN: Center for Leadership, Education and Training in Maternal and Child Nutrition, Division of Epidemiology, University of Minnesota; 2000 (Appendix C1, p. 236). http://www.epi.umn.edu/let/pubs/nmpa.shtm

Chemotherapy toxicity assessment by Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0

	Grade				
Adverse Event	**1**	**2**	**3**	**4**	**5**
Anemia	Hemoglobin (Hgb) <LLN - 10.0 g/dL; <LLN - 6.2 mmol/L; <LLN - 100 g/L	Hgb <10.0 - 8.0 g/dL; <6.2 - 4.9 mmol/L; <100 - 80g/L	Hgb <8.0 - 6.5 g/dL; <4.9 - 4.0 mmol/L; <80 - 65 g/L; transfusion indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an reduction in the amount of hemoglobin in 100 ml of blood. Signs and symptoms of anemia may include pallor of the skin and mucous membranes, shortness of breath, palpitations of the heart, soft systolic murmurs, lethargy, and fatigability.					
Nausea	Loss of appetite without alteration in eating habits	Oral intake decreased without significant weight loss, dehydration or malnutrition	Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated	-	-
Definition: A disorder characterized by a queasy sensation and/or the urge to vomit.					
Vomiting	1 - 2 episodes (separated by 5 minutes) in 24 hrs	3 - 5 episodes (separated by 5 minutes) in 24 hrs	>=6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by the reflexive act of ejecting the contents of the stomach through the mouth.					
Diarrhea	Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline	Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline	Increase of >=7 stools per day over baseline; incontinence; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by frequent and watery bowel movements.					
Fatigue	Fatigue relieved by rest	Fatigue not relieved by rest; limiting instrumental ADL	Fatigue not relieved by rest, limiting self care ADL	-	-
Definition: A disorder characterized by a state of generalized weakness with a pronounced inability to summon sufficient energy to accomplish daily activities.					
Bronchial obstruction	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic (e.g., mild wheezing); endoscopic evaluation indicated; radiographic evidence of atelectasis/lobar collapse; medical management indicated (e.g., steroids, bronchodilators)	Shortness of breath with stridor; endoscopic intervention indicated (e.g., laser, stent placement)	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by blockage of a bronchus passage, most often by bronchial secretions and exudates.					
Bronchopulmonary hemorrhage	Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated	Transfusion, radiologic, endoscopic, or operative intervention indicated (e.g., hemostasis of bleeding site)	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the bronchial wall and/or lung parenchyma.					
Bronchospasm	Mild symptoms; intervention not indicated	Symptomatic; medical intervention indicated; limiting instrumental ADL	Limiting self care ADL; oxygen saturation decreased	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by a sudden contraction of the smooth muscles of the bronchial wall.					
Cough	Mild symptoms; nonprescription intervention indicated	Moderate symptoms, medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by sudden, often repetitive, spasmodic contraction of the thoracic cavity, resulting in violent release of air from the lungs and usually accompanied by a distinctive sound.					
Dyspnea	Shortness of breath with moderate exertion	Shortness of breath with minimal exertion; limiting instrumental ADL	Shortness of breath at rest; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an uncomfortable sensation of difficulty breathing.					

Pleural effusion	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; intervention indicated (e.g., diuretics or limited therapeutic thoracentesis)	Symptomatic with respiratory distress and hypoxia; surgical intervention including chest tube or pleurodesis indicated	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by an increase in amounts of fluid within the pleural cavity. Symptoms include shortness of breath, cough and marked chest discomfort.					
Pleuritic pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation in the pleura.					
Pneumonitis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL; oxygen indicated	Life-threatening respiratory compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death
Definition: A disorder characterized by inflammation focally or diffusely affecting the lung parenchyma.					
Voice alteration	Mild or intermittent change from normal voice	Moderate or persistent change from normal voice; still understandable	Severe voice changes including predominantly whispered speech; may require frequent repetition or face-to-face contact for understandability; may require assistive technology	-	-
Definition: A disorder characterized by a change in the sound and/or speed of the voice.					
Wheezing	Detectable airway noise with minimal symptoms	Moderate symptoms; medical intervention indicated; limiting instrumental ADL	Severe respiratory symptoms limiting self care ADL; oxygen therapy or hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death

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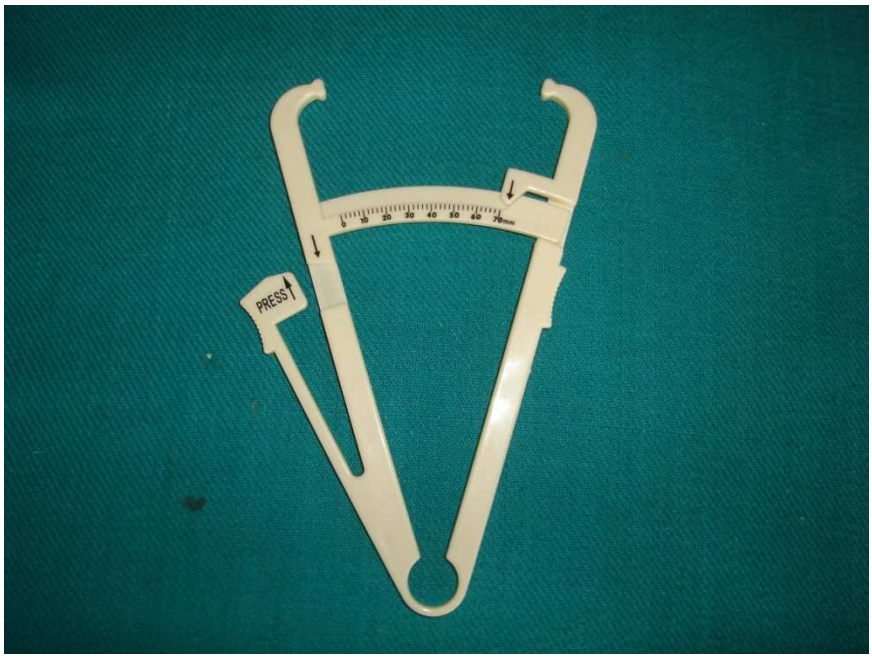
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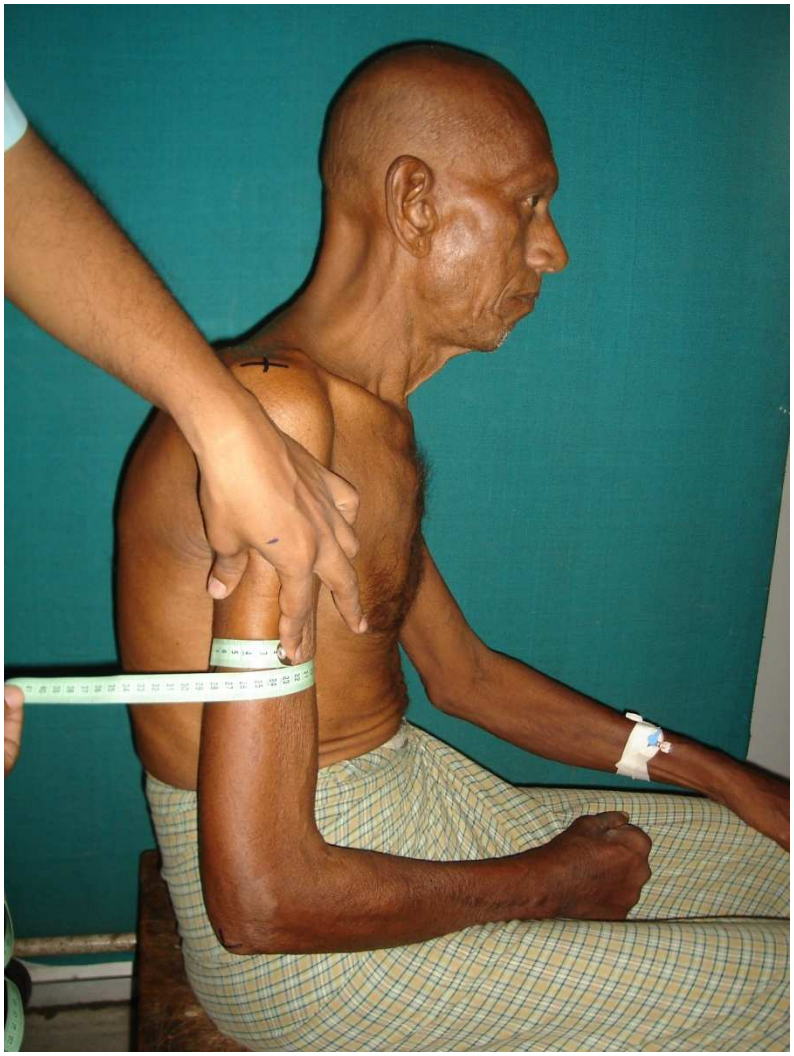

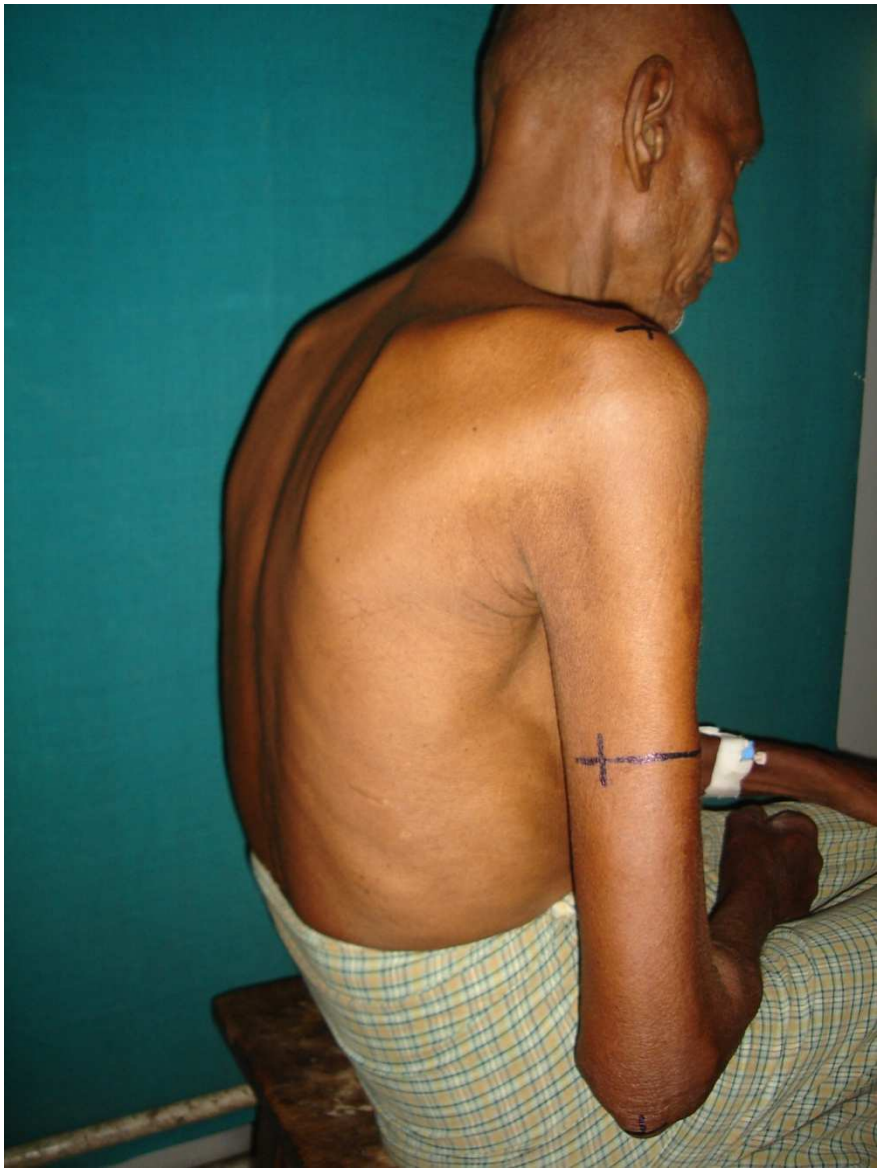


MERCK
microlab 300
paper
flush
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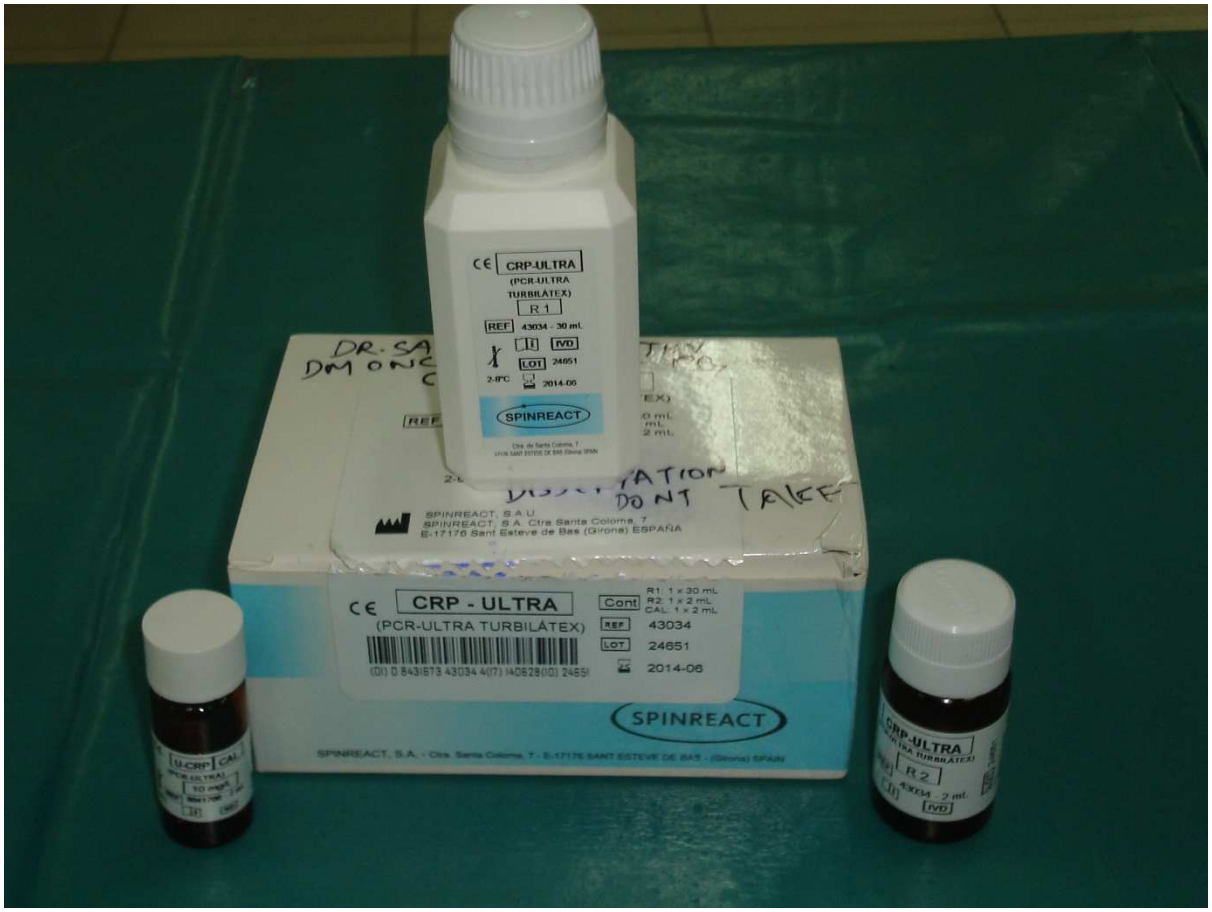
PREALBUMIN
REF A06629H
LOT 9657/012D002
2015/04
Cont Ab.Rgt.: 1x10 ml, LOT:9657/012D002
Buffer: 2x25 ml, LOT:9585/PG6214
2 - 8°C
9 120042 240910
www.diaLab.at
PREALBUMIN
LOT 9585/PG6214
2017/01
IVD
PREALBUMIN
LOT 9585/PG6214
2017/01
IVD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(PCR-ULTRA TURBILÁTEX)
R1
REF 43034 - 30 mL
LOT 24651
2-8°C 2014-06
SPINREACT
SPINREACT, S.A.U.
SPINREACT, S.A. Ctra Santa Coloma, 7
E-17176 Sant Esteve de Bas (Girona) ESPAÑA
CRP - ULTRA
(PCR-ULTRA TURBILÁTEX)
R1: 1 x 30 mL
R2: 1 x 2 mL
CAL: 1 x 2 mL
REF 43034
LOT 24651
2014-06
SPINREACT
SPINREACT, S.A. - Ctra. Santa Coloma, 7 - E-17176 SANT ESTEVE DE BAS - (Girona) SPAIN
CRP-ULTRA
R2
IVD

FACIT Administration and Scoring Guidelines

Administration:

The FACIT scales are designed for patient self-administration, but can also be administered by interview format. For self-administration, patients should be instructed to read the brief directions at the top of the page. After the patient's correct understanding has been confirmed, he/she should be encouraged to complete every item in order without skipping any. Some patients may feel that a given question is not applicable to them and will therefore skip the item altogether. **Patients should be encouraged to circle the response that is most applicable.** If, for example, a patient is not currently receiving any treatment, the patient should circle "not at all" to the question "I am bothered by side effects of treatment."

During interview administration, it is helpful to have the patient hold a card on which the response options have been printed. Interview administration is considered appropriate given adequate training of interviewers so as to elicit non-biased patient responses. One of the aims of a large multi-center study of cancer and HIV patients (N=1227) was to test the psychometric properties and statistical equivalence of the English and Spanish language versions of the FACT subscales across literacy level (low vs. high) and **mode of administration** (self vs. interview). Technical equivalence across mode of administration was demonstrated in the high literacy patients; there were no differences in data quality or in mean QOL scores, after adjustment for performance status rating, socioeconomic status, gender and age. Technical equivalence between modes of administration with the FACT permits unbiased assessment of the impact of chronic illnesses and their treatments on patients from diverse backgrounds.

Scoring the FACT-G:

The FACT-G scoring guide identifies those items that must be reversed before being added to obtain subscale totals. Negatively stated items are reversed by subtracting the response from "4". After reversing proper items, all subscale items are summed to a total, which is the subscale score**. <u>For all FACIT scales and symptom indices, the higher the score the better the QOL.</u>**

<u>Handling missing items</u>. If there are missing items, subscale scores can be prorated. This is done by multiplying the sum of the subscale by the number of items in the subscale, then dividing by the number of items actually answered. This can be done on the scoring guide or by using the formula below:

Prorated subscale score = [Sum of item scores] **x** [N of items in subscale] ÷ [N of items answered]

When there are missing data, prorating by subscale in this way is acceptable as long as **<u>more than</u>** 50% of the items were answered (e.g., a minimum of 4 of 7 items, 4 of 6 items, etc). The total score is then calculated as the sum of the un-weighted subscale scores. The FACT scale is considered to be an acceptable indicator of patient quality of life as long as **<u>overall item response rate</u>** is greater than 80% (e.g., at least 22 of 27 FACT-G items completed). This is not to be confused with individual subscale item response rate, which allows a subscale score to be prorated for missing items if greater than 50% of items are answered. In addition, a total score should only be calculated if ALL of the component subscales have valid scores.

NOTE: Computer programs written in SPSS and SAS for the FACIT scales and symptom indices are provided on diskette in Section 4 of the manual or can be downloaded from the website at www.facit.org for a nominal fee. Standard raw score scoring templates for all FACIT scales and symptom indices are also provided in Section 4 of the manual or under the "Validity and Interpretation" section of the website.

Scoring the Specific Scales & Symptom Indices:

For the "Additional Concerns" subscale (e.g., cancer-specific questions) and the symptom indices, the procedure for scoring is the same as described above for the FACT-G. Again, **over** 50% of the items (e.g., 5 of 9 items, 7 of 12 items) must be completed in order to consider each subscale score valid.

NOTE: scoring algorithms for the FACIT-TS-G and FACIT-TS-PS are different from other FACIT scales. Please refer to the specific scoring templates for more detail.

Deriving a Total Score:

The total score for the specific FACIT scales is the sum of the FACT-G (the first 4 subscales common to almost all scales) plus the "Additional Concerns" subscale. The symptom indices do not include the FACT-G in the total score. By following this scoring guide and transcribing the FACT-G score, the two totals can be summed to derive the **TOTAL FACT/FACIT SCORE**.

Notes:

1. Multilingual versions can be scored on the English language scoring guides.

2. Several scales have more items listed in the "Additional Concerns" subscale than are currently recommended for scoring. This is usually because additional work on a given subscale has suggested a need for additional items. However, it may take awhile for the new items to be validated so we don't formally recommend they be included in the scoring until we know more about how the item(s) function. We include the items on the scale to encourage investigators who have the time or resources to evaluate their data according to the existing scoring recommendations and to test out the value of the new item(s). As always, we welcome collaborators to share any relevant data of this nature to help further reliability and validity testing of the FACIT questionnaires.

Selecting Scores for Analyses:

These scoring templates allow one to obtain two different total scores in addition to each individual subscale score. The FACT-G total score provides a useful summary of overall quality of life across a diverse group of patients. The disease-specific questionnaire total scores (i.e., FACT-G plus disease-specific subscale score) may further refine the FACT-G summary score. Two alternative approaches are noteworthy, however. One is to separately analyze the FACT-G total score and the specific subscale score. Another is to select subscales of the FACT which are most likely to be changed by an intervention being tested. For example, the Physical, Functional, and Cancer-specific subscales would be most likely to change in a chemotherapy clinical trial. One could also consider creating a separate a priori index which sums two or three subscales. This has been done with the FACT-L and many other FACIT scales, combining the Physical, Functional and 7-item Lung Cancer Subscales into a 21-item

Trial Outcome Index (Cella, Bonomi, Lloyd et al, 1994; Brady, Cella, Mo, 1997; Cella, 1997). On the other hand, the Emotional or Social Well-being subscale would be expected to change most when evaluating a psychosocial intervention.

Comparing Version 4 scores to Previously Published (Version 2 & 3) Scores:

Most of the questions from Version 3 remain intact in Version 4 (see item history table in section 3 of the manual for details), although some items have been reworded and a few have changed from being negatively stated to positively stated items. Comparison between scale scores in these two versions is fairly straightforward. Adjustments must be made, however, when comparing the total FACT/FACIT score and when comparing the Emotional Well-Being (EWB) subscale score between the two versions. To compare Version 3 and 4 EWB scales, item GE6 (#25 in Version 3) must be omitted from the scoring of version 4. This can be done by scoring the first 5 items of the EWB subscale, multiplying by 5 (not 6), and dividing by the number of questions answered (not including the sixth question). The Version 4 total FACT-G score has been affected by the dropping of the Relationship with Doctor subscale and the addition in the scoring of item GE6 (#25 in Version 3). One way to compare total scores is to drop item GE6 from the Version 4 scoring and add **6.85** (mean score of the RWD subscale as reported in Cella et al., 1993) to the sum of the four subscales (Physical Well-Being, Social/Family Well-Being, Emotional Well-Being, and Functional Well-Being). This will give you the best estimate for comparison of published FACT/FACIT data.

Instructions:*
1. Record answers in "item response" column. If missing, mark with an X
2. Perform reversals as indicated, and sum individual items to obtain a score.
3. Multiply the sum of the item scores by the number of items in the subscale, then divide by the number of items answered. This produces the subscale score.
4. Add subscale scores to derive total scores (TOI, FACT-G & FACT-L).
5. **The higher the score, the better the QOL.**

Subscale	Item Code	Reverse item?		Item response	Item Score
PHYSICAL WELL-BEING (PWB)	GP1	4	-	_____	=_____
	GP2	4	-	_____	=_____
	GP3	4	-	_____	=_____
	GP4	4	-	_____	=_____
Score range: 0-28	GP5	4	-	_____	=_____
	GP6	4	-	_____	=_____
	GP7	4	-	_____	=_____

Sum individual item scores: _____
Multiply by 7: _____
Divide by number of items answered: _____=**PWB subscale score**

SOCIAL/FAMILY WELL-BEING (SWB)	GS1	0	+	_____	=_____
	GS2	0	+	_____	=_____
	GS3	0	+	_____	=_____
	GS4	0	+	_____	=_____
Score range: 0-28	GS5	0	+	_____	=_____
	GS6	0	+	_____	=_____
	GS7	0	+	_____	=_____

Sum individual item scores: _____
Multiply by 7: _____
Divide by number of items answered: _____=**SWB subscale score**

EMOTIONAL WELL-BEING (EWB)	GE1	4	-	_____	=_____
	GE2	0	+	_____	=_____
	GE3	4	-	_____	=_____
	GE4	4	-	_____	=_____
Score range: 0-24	GE5	4	-	_____	=_____
	GE6	4	-	_____	=_____

Sum individual item scores: _____
Multiply by 6: _____
Divide by number of items answered: _____=**EWB subscale score**

FUNCTIONAL WELL-BEING (FWB)	GF1	0	+	_____	=_____
	GF2	0	+	_____	=_____
	GF3	0	+	_____	=_____
	GF4	0	+	_____	=_____
Score range: 0-28	GF5	0	+	_____	=_____
	GF6	0	+	_____	=_____
	GF7	0	+	_____	=_____

Sum individual item scores: _____
Multiply by 7: _____
Divide by number of items answered: _____=**FWB subscale score**

Subscale	Item Code	Reverse item?		Item response	Item Score
LUNG CANCER SUBSCALE (LCS)	B1	4	-	_____	=_____
	C2	4	-	_____	=_____
	L1	0	+	_____	=_____
	L2	4	-	_____	=_____
Score range: 0-28 (7-item LCS)	B5	SCORING THIS ITEM NOT RECOMMENDED			
	C6	0	+	_____	=_____
	L3	4	-	_____	=_____
	L4	0	+	_____	=_____
	L5	SCORING THIS ITEM NOT RECOMMENDED			

Sum individual item scores: _____
Multiply by 7: _____
Divide by number of items answered: _____=**LC Subscale score**

To derive a FACT-L Trial Outcome Index (TOI):
Score range: 0-84

_____ + _____ + _____ =_____=**FACT-L TOI**
(**PWB** score) (**FWB** score) (**LCS** score)

To Derive a FACT-G total score:
Score range: 0-108

_____ + _____ + _____ + _____=_____=**FACT-G Total score**
(**PWB** score) (**SWB** score) (**EWB** score) (**FWB** score)

To Derive a FACT-L total score:
Score range: 0-136

_____ + _____ + _____ + _____ + _____ =_____=**FACT-L Total score**
(**PWB** score) (**SWB** score) (**EWB** score) (**FWB** score) (**LCS** score)

*For guidelines on handling missing data and scoring options, please refer to the Administration and Scoring Guidelines in the manual or on-line at www.facit.org.

FACT-L (Version 4)

கீழ்கண்டவை உங்கள் நோயைக் கொண்ட மற்றவர்கள் முக்கியமானவை என்று தெரிவித்த சில கருத்துக்கள். **கடந்த 7 தினங்களை பொருத்தவரை, உங்களுக்கு பொருத்தமாக இருக்கும் பதிலினை குறிக்க தயவுசெய்து வரிக்கு ஒரு எண்ணை வட்டமிடவும் அல்லது குறியிடவும்.**

	உடல் நலம்	**இல்லவே இல்லை**	**சிறிதளவு**	**ஓரளவு**	**கணிசமாக**	**மிக அதிகம்**
GP1	எனக்கு தெம்பு இல்லை	0	1	2	3	4
GP2	எனக்கு குமட்டல் இருக்கிறது.....	0	1	2	3	4
GP3	என் உடல் நிலை காரணத்தால் என் குடும்பத் தேவைகளை கவனிப்பது எனக்கு பிரச்சனையாக இருக்கிறது.....	0	1	2	3	4
GP4	எனக்கு வலி இருக்கிறது	0	1	2	3	4
GP5	சிகிச்சையின் பக்க விளைவுகளால் நான் அவஸ்தைப்படுகிறேன்	0	1	2	3	4
GP6	என் உடல் நிலை சரியில்லை.....	0	1	2	3	4
GP7	நான் படுக்கையில் நேரத்தை செலவிட வேண்டிய கட்டாயத்திற்குத் தள்ளப்பட்டு இருக்கிறேன்	0	1	2	3	4

	சமூக/குடும்ப நலம்	**இல்லவே இல்லை**	**சிறிதளவு**	**ஓரளவு**	**கணிசமாக**	**மிக அதிகம்**
GS1	நான் என் நண்பர்களுடன் நெருக்கமாக இருப்பதாக உணர்கிறேன்	0	1	2	3	4
GS2	என் குடும்பத்திடமிருந்து எனக்கு உணர்வுபூர்வமான ஆதரவு கிடைக்கிறது	0	1	2	3	4
GS3	என் நண்பர்களின் ஆதரவு எனக்குக் கிடைக்கிறது.....	0	1	2	3	4
GS4	என் குடும்பம் என் உடல்நலக் குறையை ஏற்றுக் கொண்டிருக்கிறது.....	0	1	2	3	4
GS5	என்னுடைய உடல்நலக் குறையைப் பற்றி என் குடும்பத்தினர் தமக்குள் தகவல் பரிமாறிக்கொள்ளுவது எனக்கு திருப்தி அளிக்கிறது.....	0	1	2	3	4
GS6	நான் என் கூட்டாளியோடு (எனது முக்கிய ஆதரவாளர்) நெருக்கமாக உணர்கிறேன்.....	0	1	2	3	4
Q1	*தற்போது உடலுறவு விஷயங்களில் நீங்கள் எப்படி இருந்தாலும், பின்வரும் கேள்விகளுக்கு தயவுசெய்து பதில் அளிக்கவும். பதில் அளிக்க நீங்கள் விரும்பவில்லையென்றால் தயவுசெய்து இந்த பெட்டியில் ☐ X பெருக்கல் குறியிட்டு அடுத்த பகுதிக்குச் செல்லவும்.*					
GS7	என்னுடைய பாலியல் வாழ்க்கை எனக்கு திருப்தியாக உள்ளது	0	1	2	3	4

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<u>கடந்த 7 தினங்களை</u> பொருத்தவரை, உங்களுக்கு பொருத்தமாக இருக்கும் பதிலினை குறிக்க தயவுசெய்து வரிக்கு ஒரு எண்ணை வட்டமிடவும் அல்லது குறியிடவும்.

	<u>உணர்வு நலம்</u>	**இல்லவே இல்லை**	**சிறிதளவு**	**ஓரளவு**	**கணிசமாக**	**மிக அதிகம்**
GE1	நான் சோகமாக இருக்கிறேன்.....	0	1	2	3	4
GE2	என் உடல் நலக் குறையை நான் சமாளிக்கும் விதம் எனக்கு திருப்தியாக உள்ளது.....	0	1	2	3	4
GE3	என்னுடைய நோய்க்கு எதிரான போராட்டத்தில் நான் நம்பிக்கை இழந்து வருகிறேன்.....	0	1	2	3	4
GE4	எனக்கு படபடப்பாக இருக்கிறது.....	0	1	2	3	4
GE5	சாவதைப் பற்றி நான் கவலைப்படுகிறேன்.....	0	1	2	3	4
GE6	என் நிலை மேலும் மோசமடையும் என்று நான் கவலைப்படுகிறேன்.....	0	1	2	3	4

	<u>செயல்பாட்டு நலம்</u>	**இல்லவே இல்லை**	**சிறிதளவு**	**ஓரளவு**	**கணிசமாக**	**மிக அதிகம்**
GF1	என்னால் வேலை செய்ய முடிகிறது (வீட்டில் செய்யும் வேலை உட்பட).....	0	1	2	3	4
GF2	என் வேலை (வீட்டு வேலை உட்பட) மன நிறைவை அளிக்கிறது	0	1	2	3	4
GF3	என்னால் வாழ்க்கையை அனுபவிக்க முடிகிறது	0	1	2	3	4
GF4	என் உடல் நலக் குறையை நான் ஏற்றுக் கொண்டிருக்கிறேன்	0	1	2	3	4
GF5	நான் நன்றாக உறங்குகிறேன்	0	1	2	3	4
GF6	வழக்கமாக விளையாட்டிற்காக நான் செய்யும் செயல்களில் மகிழ்ச்சியடைகிறேன்	0	1	2	3	4
GF7	என்னுடைய தற்போதைய வாழ்க்கைத் தரம் எனக்கு மனநிறைவை அளிக்கிறது	0	1	2	3	4

FACT-L (Version 4)

<u>கடந்த 7 தினங்களை</u> பொருத்தவரை, உங்களுக்கு பொருத்தமாக இருக்கும் பதிலினை குறிக்க தயவுசெய்து வரிக்கு ஒரு எண்ணை வட்டமிடவும் அல்லது குறியிடவும்.

	<u>மேலும் சில பிரச்சனைகள்</u>	**இல்லவே இல்லை**	**சிறிதளவு**	**ஓரளவு**	**கணிசமாக**	**மிக அதிகம்**
B1	எனக்கு மூச்சுத் திணறல் இருந்து வருகிறது	0	1	2	3	4
C2	என் எடை குறைந்து வருகிறது	0	1	2	3	4
L1	என் சிந்தனை தெளிவாக உள்ளது	0	1	2	3	4
L2	எனக்கு இருமல் இருந்து கொண்டே இருக்கிறது	0	1	2	3	4
B5	முடி உதிர்வது எனக்குக் கஷ்டமாக இருக்கிறது	0	1	2	3	4
C6	எனக்கு நன்றாகப் பசி எடுக்கிறது	0	1	2	3	4
L3	என்னுடைய நெஞ்சு இறுக்கமாக இருப்பதாக உணர்கிறேன்	0	1	2	3	4
L4	சுவாசிப்பது எனக்கு சுலபமாக இருக்கிறது	0	1	2	3	4
Q3	நீங்கள் எப்போதாவது புகை பிடித்திருக்கிறீர்களா? இல்லை ____ ஆம் ____ ஆம் எனில்:					
L5	புகை பிடித்தது பற்றி நான் வருந்துகிறேன்	0	1	2	3	4