A STUDY ON IMPROVEMENT OF QUALITY OF LIFE AFTER ESOPHAGEAL STENTING IN CARCINOMA OF ESOPHAGUS

Dissertation submitted to

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

CHENNAI - 600 032

In Partial fulfilment of the regulations
for the award of the degree of
M.S. DEGREE BRANCH - I
GENERAL SURGERY

Department of General Surgery
Coimbatore Medical College and Hospital
Coimbatore - 641 018

DECLARATION

I hereby declare that the dissertation entitled **"A STUDY ON IMPROVEMENT OF QUALITY OF LIFE AFTER ESOPHAGEAL STENTING IN CARCINOMA OF ESOPHAGUS "** was done by me in the Department of General Surgery at Coimbatore medical college hospital during the period from September 2014 to September 2015 under the guidance and supervision of **Prof. Dr. S.Balasubramanian M.S.,** Department of General Surgery, Coimbatore medical college hospital. This dissertation is submitted to the Tamilnadu Dr. M.G.R Medical University, Chennai towards partial fulfilment of requirement for the award of M.S. Degree in General Surgery. I have not submitted this dissertation on any previous occasion to any university for award of any degree.

Place:

Date:

Dr. Ponkailasam Rajam Baghavath

CERTIFICATE

This is to certify that the dissertation entitled **"A STUDY ON IMPROVEMENT OF QUALITY OF LIFE AFTER ESOPHAGEAL STENTING IN CARCINOMA OF ESOPHAGUS "** is a record of bonafide work done by **Dr. Ponkailasam Rajam Baghavath** under the guidance of **Prof. Dr.S.Balasubramanian M.S.,** Department of General Surgery, Coimbatore Medical College and Hospital. This is submitted for partial fulfilment of the regulations for the award of M.S Degree in General Surgery by The Tamilnadu Dr. MGR Medical University, Chennai. This work has not previously formed the basis for the award of a degree or diploma.

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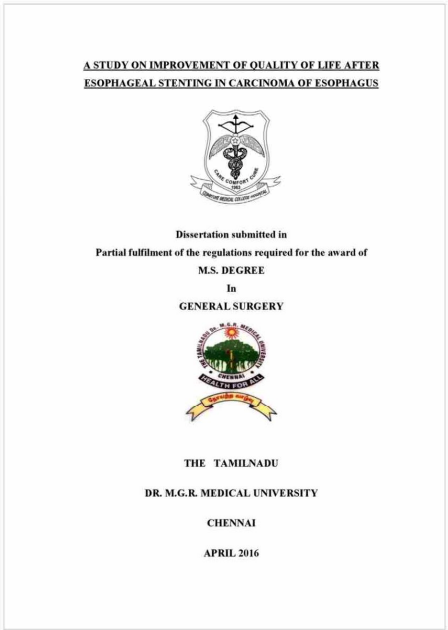

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Dr.Ponkailasam Rajam Baghavath.

A study on improvement of quality of life after esophageal stenting in carcinoma of esophagus.

Abstract

The main aim of palliation in patients with inoperable esophageal cancer is to relieve dysphagia with acceptable morbidity and mortality, and thus improve quality of life (QOL). The use of a self-expanding metal stent (SEMS) is a well-established modality for palliation of dysphagia in such patients. In our study assessed the QOL after palliative stenting in patients with inoperable esophageal cancer. Twenty one patients with dysphagia due to inoperable esophageal cancer underwent SEMS insertion between september 2014 and September 2015 in Coimbatore Medical College Hospital. All patients had grade III/IV dysphagia (n=21), In our study the procedural success rate was around 95% out of 21 patients only one patient had the complication of stent migration, which needed reinsertion.

In our study, the relief of dysphagia , general health related improvement of quality of life,and pain related improvement of quality of life were studied with the help of EORTC QLQ 30 OES 18 questionnaire,in addition to this we have studied and compared the anthropometric improvement like BMI, Biochemical improvement like, Hemoglobin ,Total proteins ,and other liver function tests, SGOT,SGPT , before and after stenting.

The dysphagia score is 6.10$\pm$1.48 before stenting ,it improved to 12.57$\pm$2.29 after 1 week,15.05$\pm$1.74,after 4 weeks and 15.57 $\pm$1.20 after 8 weeks.Thus the improvement of dysphagia before and after stenting is statistically significant.

The personal social health related quality of life score before stenting was 32.95$\pm$2.24, it improved to 26.33$\pm$3.56, after one week ,15.05 $\pm$2.22 after 4 weeks and 13.14$\pm$1.98 after 8 weeks. The improvement of health related quality of life is also statistically significant.

The pain related quality of life was 7.10$\pm$1.54 before stenting, after one week the pain got worsened and it increased to 10.00+1.97 .The worsening of pain after one week is statistically significant .After 4 weeks the pain related quality of life improved from the baseline score before stenting to 5.38,and after 8 weeks it

further improved to 4.00+0.95,These improvements in pain related quality of life too are statistically significant.

The improvement of BMI and Hemoglobin 4 weeks after stenting is statistically not significant , but 8 weeks after stenting , the improvement of BMI and hemoglobin are statistically significant

The biochemical parameters like Blood sugar, Urea are within the normal limits except for the diabetic patients, but the variation is statistically significant , before Vs 4 weeks and 8 weeks after stenting.

The variation in the creatinine values before and after stenting is not significant.

A statistically significant improvement is noted in the values of the total proteins and albumin measured at 4 weeks and 8 weeks post stenting, whereas the globulin improvement became significant only after 8 weeks.

No statistically significant changes are noted in the values of liver function tests like total bilirubin and SGOT, but SGPT values are found to be increased with statistically significant values, 8 weeks after stenting.

Key words – Esophageal stenting, SEMS, Quality of life after stenting,carcinoma of esophagus.

CONTENTS

ABBREVIATIONS

1) HRQOL – Health related quality of life

2) EORTC – European Organisation for Research and Treatment of Cancer.

3) TPN - Total Paraenteral Nutrition

4) SEMS – Self Expandable Metallic Stents

5) SEPS – Self Expandable Plastic Stents.

6) GERD - Gastro Esophageal Reflux Disease.

7) HPV – Human Pappiloma Virus

8) TEF - Tracheo Esophageal Fistula.

9) GIT - Gastro Intestinal Tract

10) HPE - Histo Pathologic Examinations

11) CT - Computerised Tomography

12) EUS – Endoscopic Ultra Sound

13) PET - Positron Emission Tomography

14) PDT - Photo Dynamic Therapy

15) QOL - Quality of Life

FIGURES

CHART

TABLES

INTRODUCTION

Esophageal carcinoma is one among the diseases with lowest five year survival rate[27],the average being only around 10 – 15 %.Only one third of the patients with carcinoma esophagus present with resectable disease at the time of diagnosis[27,2].

Majority of the patients have a fatal outcome, Where the main cause of morbidity in patients with advanced or locally advanced carcinoma esophagus is severe dysphagia[2,1], that negatively affect their nutritional status, cachexia due to carcinoma as well as dysphagia leads to the weight loss .

The important aim of treatment in patients with inoperable esophageal carcinoma is to relieve dysphagia with minimum acceptable morbidity and mortality, and thus to improve their quality of life.

Placement of a Self Expanding Metallic Stent has become the preferred treatment modality for the palliation of dysphagia due to carcinoma esophagus, because it is a minimal invasive procedure that does not need any major anesthesia and can be done with application of local anesthetics with or without iv sedation, while other surgical procedures like feeding jejunostomy and feeding gastrostomy, require major anaesthetic interventions.

Non surgical procedures like Nasogastric tube placement and feeding through them does not improve dysphagia and are poorly tolerated by the patients. The other treatment modalities to improve the nutrition like TPN(Total paraenteral nutrition) are usually avoided because of increased infection rates ,higher costs and TPN cannot be used for long period of time .

The SEMS are gaining more popularity because the procedure is easy to perform, non invasive, and has no anesthesia related complications ,

Dysphagia is relieved almost immediately after The Self expanding metallic stent placement. In most of the researches and studies, that were conducted to study the outcome of improvement in quality of life after placement of Self expanding metallic stent in patients with carcinoma esophagus, dysphagia relief is the only indicator used in measuring the improvement of quality of life, while other indicators that can affect general health and the health related quality of life of the patients ,including the physical, mental and social wellbeing of the patients and the biomedical parameters, before and after the stent placement were not adequately explored. Keeping this point in our mind ,In this study we evaluated not only the improvement of dysphagia after stenting , but also the pain, health related quality of life(HRQOL) improvement along with the improvement and changes of various other health related indicators , biochemical parameters that can affect the quality of life were studied and evaluated by a questionnaire, intervention and laboratory based results and analysis .

AIMS AND OBJECTIVES:

- To characterize patients posted for stenting as palliative measure for dysphagia due to carcinoma of esophagus

- To compare quality of life of patients with carcinoma of esophagus with dysphagia before and after esophageal stenting

- To evaluate clinical predictors of improved quality of life after stenting .

REVIEW OF LITERATURE

Carcinoma esophagus is the sixth most common cancer in the world[1] .The carcinoma esophagus is a disease of mid and late adulthood[2]with a poor survival rate ,it is an extremely aggressive and fatal cancer[27] disease that is least studied. It has very poor 5 year survival rate (around 10 %) according to some literatures and some text books. Studies[27] suggest that the survival rate could be much lower than 10 % , Carcinoma of the esophagus is seventh leading cause of death due to malignancies .The most common pathologic types, are squamous cell carcinoma and adenocarcinoma.

The incidence of carcinoma esophagus accounts for one percent of all malignancies and six percent of all the Gastro intestinal malignancies . Worldwide, squamous cell cancer is most common, but adenocarcinoma is nowadays more often diagnosed in the western world. Its incidence is rising in those countries[27].This may be due to the life style change occurring over past few decades ,including changing food habits, obesity due to sedentary life style, which are in turn the risk factors of GERD[1,2,27].

Geographical variation in oesophageal cancer:

The incidence of esophageal carcinoma is different it varies for different area and countries, Which is the unique feature of carcinoma esophagus .The change is more when compared with other cancers[2]. Squamous cell cancer is seen endemic in South Africa in its region called

Transkei and also widely seen in The Asian 'cancer belt' that area starting from the middle of Asia, from the Caspian Sea (Iran northern region) to China[2]. The highest incidence rate in the world is in the Henan province located in China particularly in a place called Linxian[2].,Most deaths have occurred there due to carcinoma esophagus which even became, a single leading cause of death. More than 100 cases per 100 000population are diagnosed there per year[2], The specific cause of carcinoma of esophagus in those endemic areas is not clearly known, but it is suspected that it may be due to a combination of contamination of food with some fungi and deficiencies in several nutrients It is noted that in certain areas, the supplementation of the food with certain nutrients ,including selenium, vitamin E, and beta carotene resulted in the decrease in the incidence of the disease[2,1].

But drinking alcoholic beverages , hot food , consumption of tobacco in any form, including chewable or smoked are the main risk factors in certain others other areas for the occurrence of squamous cell carcinoma. Incidence rates vary from less than five per 100000 in the white people in USA to, 26 :100 000 in some areas of France.

In India the incidence rate widely varies from state to state[28] ,it is highest in the state Kashmir about 70/100000. In Mumbai it accounts for 20/100000,whereas in Bangalore it is 11/100000. Highest Female : male

(more than 5 per 100,000 person-years) were reported from Bombay, in India; Shanghai, in China[28]; and in some regions of united kingdom. The disease is often seen rising with age, reaching its peak in the sixth to seventh decade of life[2,1].

World wide ratio ,Male : Female = 3.5 : 1 .In The United States[2], and many other Western Nations, the incidence is now increasing. in the past few decades with a more profound increase in the incidence rates of adenocarcinoma, Though the squamous cell carcinoma predominates all over the world.

Though it is appropriate to plan the treatment according to their pathologic types of malignancy, still they are mostly treated like single entity[2]. Todays treatment interventions have limited effect on the survival, and the case fatality rate nears almost 90%. Though carcinoma esophagus is diagnosed increasingly after the widespread use of upper GI endoscopy[1,2] , the disease is often inoperable and the main aim of the treatment is palliation rather that a curative one[2,1,27]

A study conducted at Coimbatore Medical College Hospital , Coimbatore, India in the year 2013 revealed out of 50 patients evaluated with endoscopy for dysphagia , 16 patients were found to have carcinoma esophagus .Among those 16 patients curative esophagectomy was possible in

only one .Rest were treated with non surgical procedures, including stenting and chemotherapy.

Anatomy of the esophagus

Esophagus is the muscular tube extending from the base of pharynx at C 6 to the cardia of stomach at T 11 .It is about 25 to 30 cm length and average inner luminal diameter of 23 to 30 mm. Esophagus has got three parts cervical, thoracic and abdominal, as it passes a through the above region in its course. Total length of the esophagus is also divided as upper, middle and lower third, roughly 8 cm each in surgical anatomy.

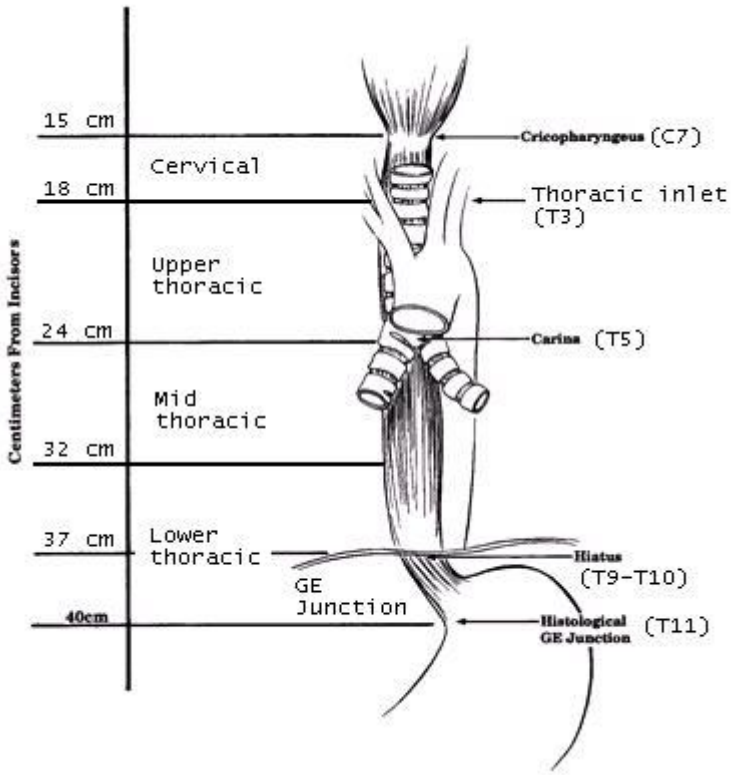
The cervical esophagus starts from cricopharyngeus and extend upto horizontal part of inferior constrictor muscle. Trachea and recurrent laryngeal nerve are the main structures related to cervical part. Thoracic esophagus starts from the right side but it deviates to the left side and continues as abdominal part. It is related to azygos vein, thoracicduct, aorta,pleura and pericardium.

In neck and thorax it is related to vertebral column posteriorly and trachea anteriorly. At the carina, heart and pericardium lie directly anterior to the thoracic esophagus. Upper esophageal sphincter and lower esophageal sphincter are the two high pressure zones in cranial and caudal part of esophagus respectively. Esophagus enters the abdominal cavity through the

esophageal opening in the diaphragm at the level of T10. Along its course the esophagus has three constrictions , First one is the narrowest point at cricopharynx, which has 14 mm inner diameter. It is the narrowest part of the gastro intestinal tract and situated 15 cm from the upper incisor .

Second esophagus constriction is broncho aortic constriction at the level of T4, situated roughly at 25 cms from the upper incisor, It is also the commonest site of perforation during endoscopic procedures. The third constriction is diaphragmatic constriction at the point where it enters the abdomen at T10 level and 40 cm from the upper incisor.

Fig.1 Esophagus divisions

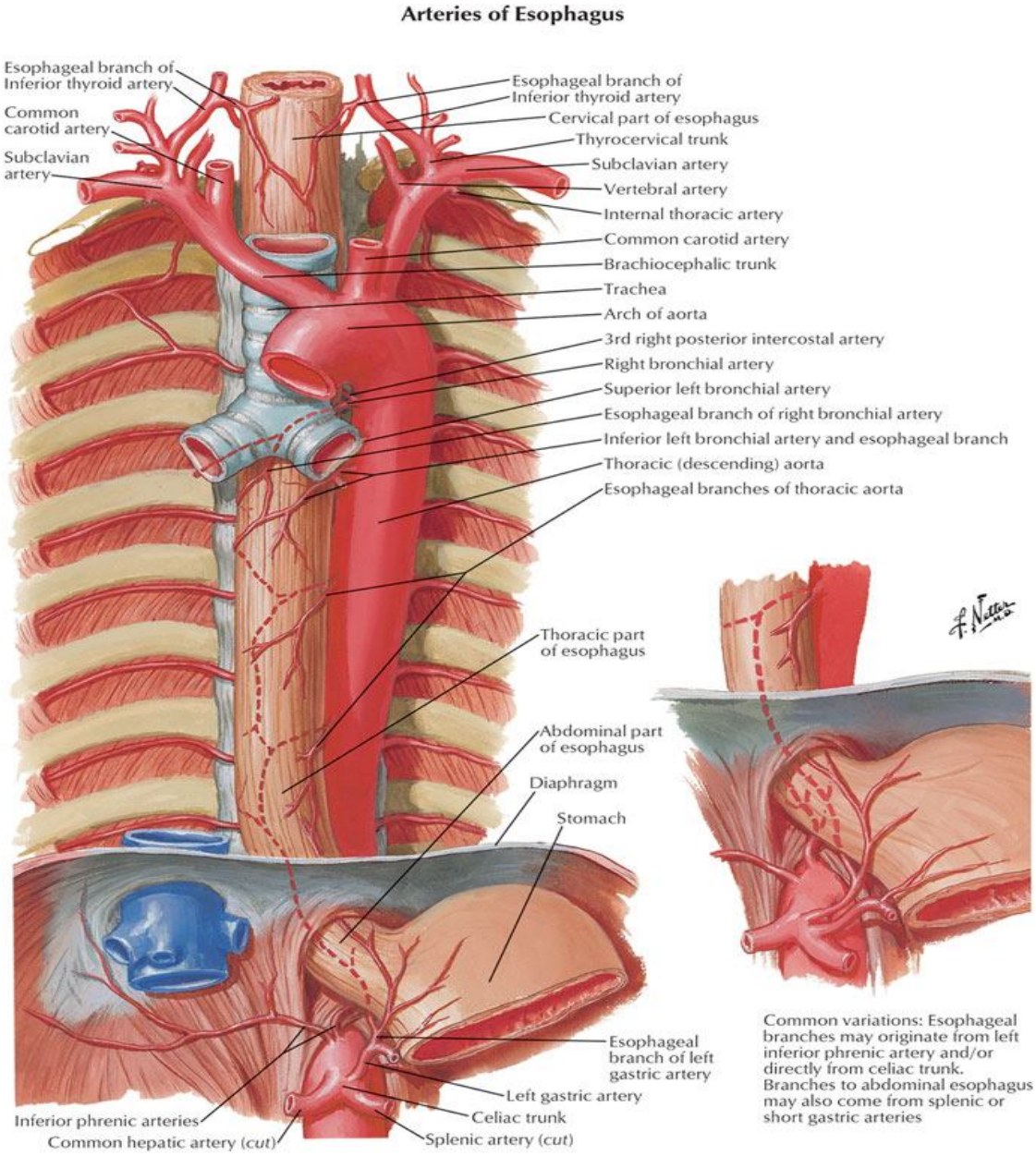


Blood supply of the esophagus:

Cervical part of the esophagus is supplied by Inferior thyroid artery. Thoracic part is supplied by direct branches of aorta and the esophageal branches of bronchial arteries, Supplemented by inferior thyroid artery, intercostal arteries and inferior phrenic arteries.

Abdominal part of the esophagus derives its blood supply from left gastric artery and Inferior phrenic artery, Esophageal branches in this part either arise from inferior phrenic or celiac trunk. All the arteries form a capillary network that continues along the full length of the esophagus within the submucous layer.

Fig 2.Arteries of esophagus.



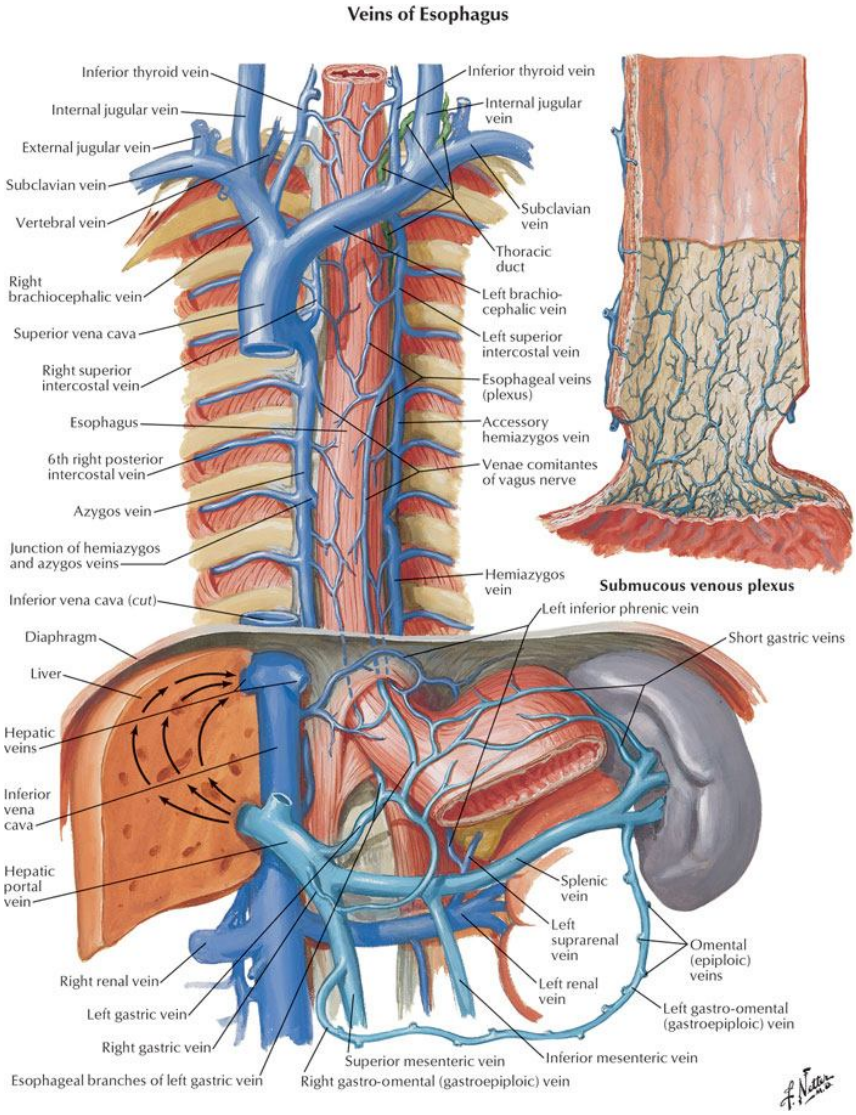
Venous drainage of the esophagus:

Submucous venous plexus, which extends through the whole length of the esophagus is the first basin for venous drainage.

Cervical part of esophagus is drained by Azygos vein on the right side. Abdominal part of the esophagus is drained by Left and right phrenic veins of systemic circulation and Left gastric and short gastric veins of portal circulation.

Venous system of the esophagus in its lower end is one of the junction of the portal and systemic circulation.

Fig 3 .Veins of esophagus



Lymphatic drainage of the esophagus

Interconnecting lymphatic plexus in the submucous and muscular layer of the esophagus drains in to the regional nodes. Because of the longitudinal arrangement of the lymphatics, spread to the distant nodes occurs early in case of carcinoma of esophagus.

Cervical part of the esophagus drains in to

- Paratracheal nodes anteriorly
- Deep cervical laterally
- Internal jugular posteriorly

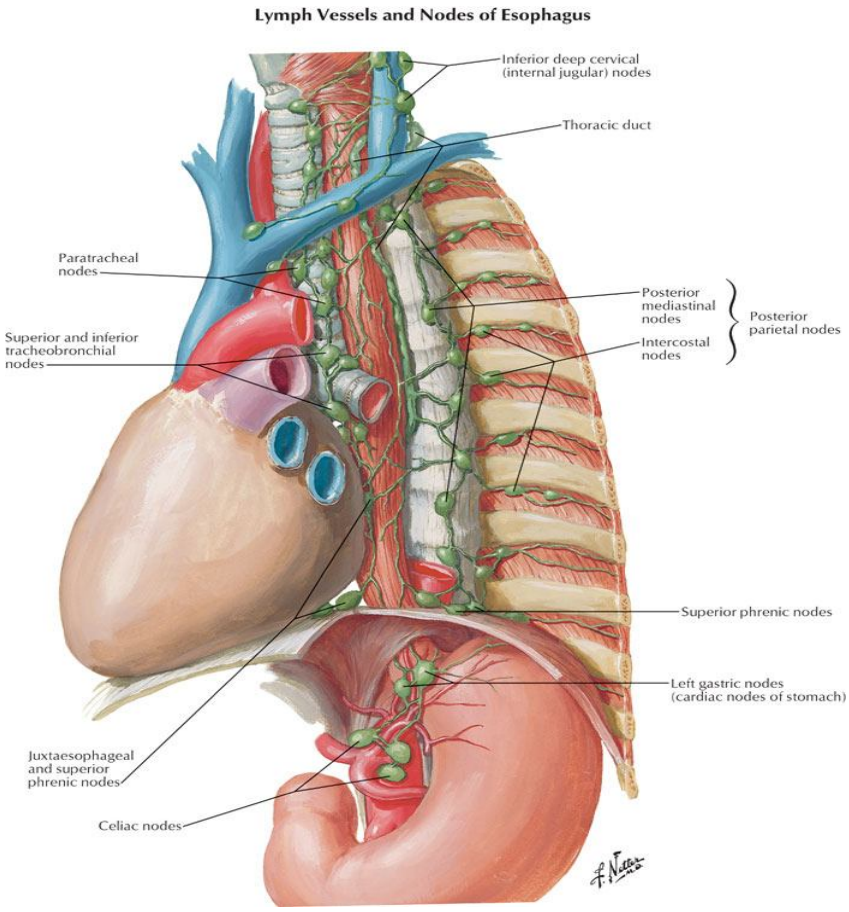
Carcinomas of the cervical and upper third of the thoracic esophagus drain into the cervical and superior mediastinal lymph nodes

Thoracic esophagus drains in to

- ❖ Mediastinal nodes
- ❖ Thoracic duct
- ❖ Paratrachealnodes
- ❖ Subcapital nodes
- ❖ Paraesophageal nodes
- ❖ Retrocardiac nodes
- ❖ Infracardiac nodes
- ❖ Para aortic nodes
- ❖ Inferior pulmonary ligament nodes

The knowledge of lymphatic drainage of esophagus is very important because, the surgical approaches for esophageal cancer are based on the anatomy of the lymphatic drainage of esophagus. That is why some specific surgical procedure is recommended , based on the cancer site in the esophagus .

Fig 4.Lymph vessels and Nodes of esophagus.



Innervations of the esophagus :

Autonomic nervous system innervates the esophagus like it does to the other parts of gastro intestinal tract for the motility and the secretion functions.

Sympathetic innervation.

Sympathetic innervation has inhibitory action on esophagealmotility and excitatory action on its sphincters. Superior ganglion of the cervical sympathetic trunk innervates the cervical esophagus.

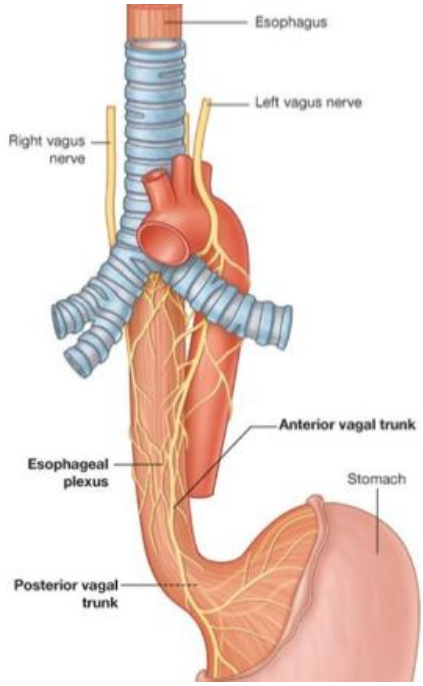
The upper part of the Thoracic esophagus is innervated by the stellate ganglion of cervical sympathetic trunk ,the lower part is innervated by lesser splanchnic ganglion .

The Abdominal part of the esophagus is innervated by the sympathetic fibers along the left gastric artery.

Parasympathetic innervation.

Vagus nerve provides the parasympathetic innervation for motility and secretory functions and has inhibitory effect on sphincters . Two plexus of nerves known as Auerbach' smyentric and Submucous Meissner'splexus , are very sparse in the esophagus as compared to other parts of the Gastro Intestinal Tract.

Fig.5 Nerves of esophagus.



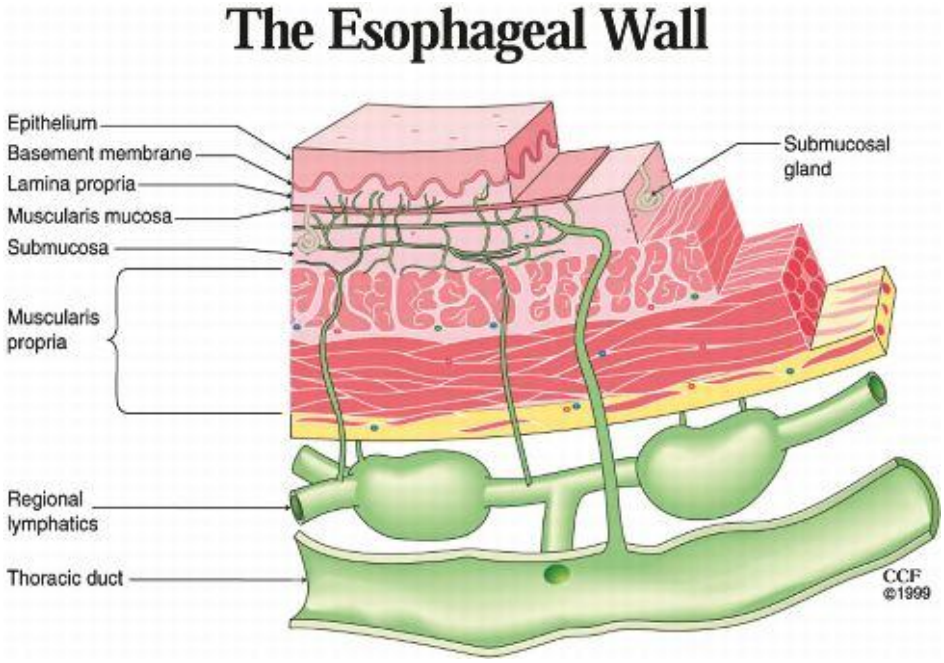
Esophagus Histology

Esophagusis predominantly composed of muscular tissue

Esophagus has the following layers

- Mucosa
- Basement membrane
- Lamina propria
- Muscularis mucosa
- Submucosa
- Muscularispropria
- Advential layer

Fig.6.Esophageal wall.



Mucosal Layer

Inner most layer of the esophagus is the mucosal layer. It is lined by squamous epithelium except in the distal 1 or 2 cm where it is replaced by transitional or junctional columnar cella at the Z line.

Epithelium, basement membrane ,laminapropria and the muscularismucos are the parts of mucosal layer.

Submucosa

Submucosa is deeper to the mucosa and it contains lymphatics, vascular structures ,mucous glands and Meissner's plexus of nerves.

Muscular Layer

There are two layers of muscularispropria , the inner circular and the outer longitudinal. These layers are striated in the upper 1/3rd and smooth muscle in the lower 2/3rd .

The circular muscles are the extension of cricopharyngeus muscle. Transition of the circular muscle of the esophagus to the oblique muscle of the stomach is at the incisura is called as the ‘coller of Helvetius’ Between the muscular layers of the esophagus there are connective tissue ,blood vessels and the Auerbach’s plexus. Esophagus has no serosal layer. It is wrapped by fibroalveolar adventitial layer.

Physiology of the esophagus .

The esophagus transports materials from the pharynx to the stomach, It restricts amount of air that swallowed and amount of the food material that is regurgitated backward from the stomach.

In normal physiological conditions the esophagus allows easy effortless unidirectional flow of the food materials towards the stomach. The upper esophageal sphincter is 4-5 cm long and has average resting pressure of 60 mm Hg , that prevents excess aerophagia.

The lower esophageal sphincter is 2-3 cm in length and has average resting pressure of 6 to 26 mm Hg, that prevents excess regurgitation of food from the stomach. Function of the lower esophageal sphincter is influenced by various factors like gastric distension, alcohol consumption tobacco , and hormonal variations.

Physiological events of deglutition in the esophageal phase. The food is propelled by the relaxation of the upper esophageal sphincter and constriction of the posterior constrictor .Upper esophageal sphincter closes

with pressure of 90 mm Hg, which prevents regurgitation of bolus to the pharynx.

Post relaxation contraction of the upper esophageal sphincter initiates primary peristalsis. The primary peristalsis moves in 2-4 cm/sec .Within 9 secs the food bolus reaches the lower esophageal sphincter. The secondary peristalsis is progressive and initiated by the distension and irritation of esophagus, to clear up material that left behind after the primary peristalsis

The Tertiary peristalsis is a non progressive one , that occurs following voluntary swallowing or between swallows, that is uncoordinated and esophageal spasm.

The lower esophageal sphincter is relaxed by vagal stimulation and that lasts for 3 to 6 sec that allows the transport of the food bolus from the esophagus to the stomach.

Lower esophageal sphincter returns to the resting tone that prevents regurgitation.

Etiology of Carcinoma of the esophagus

- The tobacco consumption in any form ,including chewing, smoking and alcohol consumption are the main risk factors for carcinoma of esophagus, especially the squamous cell carcinoma all over the world,[1,2]

- Dietary deficiencies of certain nutrients particularly the vitamins A,C,E and deficiency of minerals ,like zinc, selenium and molybdenum also play a major role in the development of carcinoma of esophagus[1,2.]
- Consumption of spicy pickled ,smoked foods with increased contents of nitrosamine , habits of taking very hot beverages, also play role in causing carcinoma esophagus ,commonly the squamous cell carcinoma.
- Carcinoma also arises from the mucosal injury caused by caustic ingestion.
- Plummer winson syndrome or Peterson Kelly syndrome characterized by the presence of esophageal webs, iron deficiency anemia, cheilitis and koilonychia is considered a risk for developing carcinoma esophagus[1,2].
- Tylosis – a familial syndrome characterized by increased thickening of palms and soles are associated with the increased risk of developing squamous cell carcinoma[1,2].
- GERD and obesity leads to decreased tone of LES that in turn cause acid reflux that causes chronic irritation of esophageal mucosa , which leads to metaplasia and dyplasia (Barret's esophagus) which is a risk factor for developing adenocarcinoma[1,2].

- Presence of anatomical abnormalities like stricture, diverticula, and motility disorders including Achalasia also increases the risk of malignancy[1,2].
- The presence of other malignancies in the aerodigestive tract also increases the risk of malignancy in esophagus[,2].
- Several studies now suggest that H .pylori infection particularly with the cag A strains are risk for developing adenocarcinoma , several studies conducted in South Africa also suggest that high prevalence of carcinoma esophagus in some areas where HPV infection plays role in the etiology[,2].

Clinical features of carcinoma esophagus:

Clinical Presentation

Most malignancies of the esophagus present with the cardinal symptom that is dysphagia or difficulty in swallowing its presence indicates that the disease is in the advanced stage, 50% of the esophageal lumen is usually occluded during the presentation of this symptom[1,2,27,].

In the earlier stages the symptoms are often just mimic the GERD or Gastro esophageal reflux disease[1,2],patient often complains of feeling of fullness, indigestion, early satiety, vomiting , nausea and burning sensation in the retrosertnal area. some times these patients may present with breathing difficulty, or like asthma due to regurgitation of contents in to the respiratory tract.

Signs and symptoms of aspiration and severe dyspnea may also present if the disease is complicated with tracheoesophageal fistula formation[1,2].

The patients also present with pain during swallowing or odynophagia, The main symptoms associated with difficulty in eating and tumour related cachexia often lead to loss of weight, the patients are often sick looking ,emaciated with severe morbidity.

Carcinoma esophagus should be ruled out by doing endoscopy investigation while the patients are evaluated for anemia that is associated with or without dysphagia. In the advanced stages hoarseness of voice may present in case of recurrent laryngeal nerve is involved, and Horner's syndrome in case of sympathetic trunk involvement[1,2].

Bone pain and paralysis of diaphragm are the signs if the disease well advanced. Involvement of the supraclavicular nodes and skin changes are suggestive that the disease is a disseminated one .The disease is inoperable if these symptoms are already present[1,2].

Some patients with GERD and Barret's esophagus are evaluated with endoscopy and diagnosed during the surveillance procedures[1,2]. But these group of people are rare in the developing countries like India, In our country the people seek medical help only when they develop symptoms, and at that time they have already reached the advanced the stages and most of them are inoperable at that moment unfortunatlely.

Diagnosis and investigations[1,2]:

The carcinoma of esophagus is often diagnosed during the upper GI endoscopy procedure. [1,2]

By the upper GI endoscopy we can obtain the informations like

- Site of the leision measured as distance from the incisor teeth.
- Physical appearance of the tumour , like polypoidal, ulcerative, or ulcereoproliferative etc.
- Extent of the tumour
- Relationship with the cricopharngeal muscle, OG junction and stomach.
- And the status of stomach is also studied.

The improved image resolution of modern endoscopes and novel techniques involving magnification and the use of dyesto enhance surface detail may lead to more early lesions beingrecognized.

If the suspected growth is seen during the endoscopy examination, tissue biopsy is taken and sent for Histopathologic examination, and the diagnosis is confirmed with type of the cancer and its grade.

General assessment and staging

- ❖ Squamous cell carcinoma usually affects the upper two-thirds; adenocarcinoma usually affects the lower third
- ❖ The incidence of adenocarcinoma is increasing

- ❖ Lymph node involvement is a bad prognostic factor
- ❖ Dysphagia is the most common presenting symptom, but is a late feature[1,2]
- ❖ Accurate pretreatment staging is essential in patients

The carcinoma of esophagus in the very early stage is usually without any symptoms, But by that time itself the malignancy tends to spread .The symptoms like difficulty in swallowing , excessive heartburns and pathologic significant loss of weight appear only when the tumour has become already advanced , by that time only unfortunately it is often diagnosed .This character is common to the both of the histopathologic variants the adenocarcinoma and the squamous cell carcinoma.

The spread of the esophageal malignancy occur by direct invasion in to the adjacent organs and structures , This is facilitated by the absence of the serosal layer of esophagus, it can also spread through the lymphatic system, or through the blood , These are the important three ways through which the esophagus malignancy spread.

The esophagus is rich in the lymphatics which are present within its wall itself known as the submucosallymphatics. This is one of the main differences with the other parts of GIT, where the lymphatic system is in segmental pattern. That is why skip leisions are more common in the esophagus , and the spread through the lymphatic system can occur in all directions , but commonly in the caudal direction. The involvement of lymph

nodes vary from the mediastinal to the celiac. The esophageal malignancy can spread through the blood to different organs ,more often to the lungs, liver brain and the bones . The transperitoneal spread is also possible if the location of tumour is in the abdominal esophagus.

When the patients are diagnosed with carcinoma ,they undergo detailed clinical examinations to asses their overall health status , including nutritional status comorbidities , so that the treatment for the particular patient can be planned. Fitness is very important to undergo surgical treatment like esophagectomy since the surgery related morbidity and mortality are high. Palliation for the purpose of improving the quality of life of the patient is planned for the patients with poor nutritional status , poor fitness, and with advanced disease .

Chemoradiotherapy may be planned for the patients with squamous cell carcinoma after improving their nutritional status and quality of life by palliative procedures like SEMS placement, etc.

The patients with early disease and fit to undergo curative definitive procedures are evaluated further to diagnose the accurate staging of the disease. The are investigated for distant metastases and the local advancement is also assessed .

Evaluation of local advancement:

The endoscopic ultrasound investigations with or without laparoscopy procedure is performed to assess the local advancement status of the disease. By this investigation T staging of the leisions are diagnosed. The treatment is planned according to the TNM staging of the disease[1,2].

For the T1 and T2 leisions definitive curativesurgical procedure Esophagectomy isusully planned and for advanced lesions (T3/T4, N1) treatment is individually planned ,

Table TNM staging scheme for esophageal cancer

- Tis is High-grade dysplasia
- T1 If the Tumourextends to lamina propria or submucosa
- T2 Tumour invades the layer muscularispropria
- T3 Tumour invades beyond the layer muscularispropria
- T4 Tumour invades all the layers then to adjacent structures
- Tx IF the Primary tumour cannot be assessed
- N0 IF there is no regional lymph node metastases
- N1 If the Regional lymph node metastases are present
- Nx If the Lymph nodes cannot be assessed
- M0 IF there is no distant metastases
- M1(a) Coeliac node involved (for distal esophageal tumours)
- Supraclavicular node involved (for proximal tumours)

- M1(b) Coeliac or supraclavicular node involved if not remote from tumour site (i.e. not 1a)
- Mx Distant metastases cannot be assesed

The correct and accurate T staging and N staging are often can be done only after the esopgahectomy with lymphadenectomy and after the HPE of the specimen is done.

Some times The patients described as N0 before surgery may become N1,after the HPE examination this is known as stage migration.

Staging information are done before the treatment is started, during the treatment (e.g. at open surgery) or

Following the treatment (HPE or Autopsy).

Blood tests

These are part of the routine investigation plan. Blood tests are not useful for the evaluation of localinvasion , lymph node spread .

There are no specific tumour markers available to suggest the carcinoma esophagus. The liver function tests abnormalities may give some clues regarding the liver metastases, but these are non specific.

Transcutaneous ultrasound and Chest x ray:

It is These investigations is nowadays performed as a routine the USG usually uses low-frequency sound waves, thus the trans cutaneous ultrasound may diagnose the Haematogenous spread , asses the status of

intra abdominal solid organs including liver, spleen, pancreas .The chest x-ray may detect the lung metastases but with the computerized tomography these investigations are less accurate. [1,2]

Bronchoscopy

The carcinomas of the esophagus involving the middle third- and upperthird of the esophagus are mostly squamous cell carcinomas they are relatively fast growing and fast spreading tumours , they invade the adjacent structures including the trachea ,and bronchi , in such conditions the bronchoscopy is useful in diagnosing the invasion of respiratory tract by the esophageal carcinoma. This may be useful for planning the further treatment strategies[1,2].

Laparoscopy

This is an invasive procedure usually done under the general anesthesia , it diagnoses the peritoneal seeding , carcinomatosis ,liver metastases etc . Tissue biopsies are taken using the laparoscope. It is done if the carcinoma arises from the abdominal esophagus[1,2].

Computerised Tomography

It is an additional diagnostic tool used for the more accurate diagnostic staging of carcinoma of esophagus .CT chest provides with detailed information about size and the extent of leision , thickness of esophagus. It also gives the information about the regional lymph node status

and also it can diagnose the distant metastases to other organs , including liver, lungs etc. In the T4 leisions, it is useful in assessing the local invasion. Fistula and the anatomical variations can also be diagnosed and is the modality most used to identify haematogenous metastases (Fig. 59.48). Distant organs are easily seen and metastases within them visualised with high accuracy (94–100%). The normal thoracic oesophagus is easily demonstrated by CT scanning. Nowadays with the use of spiral and thin slice CT small size lymph nodes up to 5mm are also diagnosed more accurately.But it cannot differentiate whether the nodes are metastatic or inflammatory[1,2] .

Magnetic Resonanceimaging :

Magnetic resonance imaging (MRI) is not routinely done in the patients with carcinoma of esophagus, the advantage of MRI is it uses no ionizing radiation and iv contrast drugs also not needed. The thickness of the esophagus is assessed by the air that present in side lumen of the esophagus .The intra hepatic leisions and other soft tissues are very well assessed by the MRI , thus metastases are diagnosed more accurately[1,2].

Endoscopic ultrasound

It is an one more diagnostic tool used to assess the staging of carcinoma of esophagus, the length and depth of the tumour can be assessed by the EUS .These are very important in staging the disease , because it

gives the information about how deep the tumour is penetrated in to the esophagus wall and to the adjacent anatomical structures. This information is useful for assessing the prognosis factors . The advantage of Endocopic ultrasound over the CT scan that has limited axial resolution is the ability of EUS in assessing the depth ,invasion and the involvement of the regional lymph nodes. The T 1 stage and T3 stage and the T4 staging are very well diagnosed by the EUS , that cannot be done with the cutaneous ultrasound. Narrow EUS instruments are available for insertion over a guidewire to minimize the risk of technical failure, and linear array echo endoscopes can be used to biopsy lesions that might signify incurability outside the wall of the gastrointestinal tract[1,2]

(e.g. coeliac lymph nodes)..

When used in isolation, there are problems with the anatomical location of these areas. This has been significantly improved by combining PET with CT . Although there are wide variations between centres, a change in stage is frequently reported in around 15% of patients. It has also been suggested that a reduction in PET activity following chemotherapy might be a way of predicting ‘responders’ to this approach. .

Positron Emission Tomography/computerised tomography scanning[1,2]

(PET) is an another diagnostic modality it can detect the tumour by the high metabolic activities that occur in the tumour cells.

This is done by the administration of radiopharmaceutical drug known as 18 F- fluorodeoxyglucose to the patients. After entering in to the tumour cells it got phosphorylated , the phosphorylated FDG 6 phosphate gets accumulated in the cells where the metabolic activity is very high, since it is not metabolized further. The carcinoma of esophagus are also metabolically very active and easily visualized by the PET scan this is achieved better by its combination with the CT , rather that using it isolated accumulates in metabolically active cells. Primary esophageal cancers are usually sufficiently active to be easily visible, and spatial resolution of positive PET areas occurs down to about 5–8 mm. When used in isolation, there are problems with the anatomical location of these areas. This has been significantly improved by combining PET with CT [1,2].

Treatment of Carcinoma esophagus:

Treatment choices of carcinoma of the oesophagus[2]

- Radical oesophagectomy is the most important aspect of curative treatment
- Neoadjuvant treatments before surgery may improve survival in a proportion of patients
- Chemoradiotherapy alone may cure selected patients, particularly those with squamous cell cancers

- Useful palliation may be achieved by chemo/radiotherapy or endoscopic treatments. [1,2]

Principles for treatment:

For the early cancers with T1- T2 staging esophagectomy with lymphnode dissection gives better cure rates , but the procedure should be done precisely to avoid the staging error and to decrease the local recurrence rate[,2] .

Studies, that were conducted in Japan suggest that esophagectomy done with curative intent and with adequate lymphnode dissection improves the survival rate. The curative esophagectomy procedure should give importance to adequate margin clearance of 10 cm above the cancer macroscopically and 5 cm to the cancer distally. Local recurrence are more common if such adequate margin clearance is not possible squamous cell carcinoma, is esophagectomy is often followed by postoperative radiotherapy avoids the local recurrence, but in such cases the survival is not improved.

Adenocarcinoma commonly involves the lower third of esophagus and tend to metastasize to liver often, it may also involve the cardia, and fundus of stomach, so during esophagectomy for such patients the portion of the stomach is also excised for the purpose of achieving margin clearance and lymphnode[1,2]dissection,may therefore extend into the fundus or down the lesser curve

Most of the patients with carcinoma esophagus when diagnosed, present with inoperable disease .This inoperability rate accounts for about 60% to 70 % .

The main aim of treatment in such patients is the palliation. The palliative treatment procedures are aimed to relieve or improve the dysphagia , which is one of the most distressing symptoms of carcinoma of esophagus and its relief that is restoration of swallowing function is needed to improve the quality of life of the patients.

The patients with advanced carcinoma of esophagus usually have low survival rate , and the palliative procedure that suits particular individual patient is planned according to his need. The tumour site its morphology , fitness of the patient, nutrition status of the patient are considered before planning a palliative procedure.

In carcinoma esophagus even T2 leisions can spread to the local lymph nodes , because of the submucosal lymphatics present in the esophagus.

The Barret's esophagus with high grade dysplasia often becomes malignant, so if it is diagnosed , and the fitness of the patients are also good then esophagectomy is the best suited procedure.

Surgical Treatment procedures with curative intent:

The Surgical procedure done for the carcinoma of esophagus is Esophagectomy[2].Mostly this procedure is planned for the fit patients with

T1 , T2 disease ,and have nonodal spread (N0). The preoperative investigations are very well planned to accurately stage the disease, Esophagectomy alone done and adequate for the patients with the staging T1 NO Mo . The cure rate achieved in those patients is around 55% to 75 %

Multi modal treatment is planned for the patients who have advanced disease staging .Such patients are treated with Neoadjuvant chemo radiation therapy or post operative adjuvant chemo radiation[1,2].

It is important that esophagectomy should be performed with a low hospital mortality and complication rate. Case selection, volume and experience of the surgical team are all equally important.

Preoperative risk analysis has shown that this can play a major part in reducing hospital mortality. The following Surgical procedures are done for tumours in the mid and distal esophagus

Transthoracic surgical procedures :

1) Ivor Lewis operation [2]
   - Right thoracotomy is combined with the laparotomy
2) McKeownoperation[2]
   - Right thoracotomy is done combined with laparotomy, and cervical approach and anastomosis is done.
3) Left thoracotomy[2]
4) Left thoracoabdominal

The type of the cancer its site the extent of lymphnode dissection are important factors that influence the prognostic outcome of the disease.

The left thoraco abdominal approach is very difficult to perform due to the aortic arch which is situated proximally, therefore the surgery is often not feasible if the tumour is in the upper esophagus..

Non surgical Treatment Procedures:

1)**Photo DynamicTherapy (PDT)** [2]

The photodynamic treatment is an treatment modality, often planned for the patients who are not fit for surgery . This is an endoscopic procedure, a photosensitiser is administered to the patients and it is taken up by the tumour cells . Then the tumour is exposed to the laser light . The tumour ablation is done in such way has so many adverse effects too, including skin photo sensitisation, stricture formation.etc.

Non-surgical treatment methods:

Radiotherapy was the only treatment modality that was used until 1970.It was mostly used for the treatment of squamous cell carcinoma .The five year survival was very low and less than 6% for the patients who were treated with radiotherapy alone. So studies were focused on the multimodal treatment procedures, and multimodal treatment was given to patients later in the 1980s,combined with chemotherapy the survival rate of squamous cell carcinoma was on par with the esophagectomy surgery. But the

treatment is not a curative one, the local recurrent rates were very high, so the treatment with surgical procedures gained importance.

The chemo-radiation treatment was often reserved for surgically unfit patients, Theesophagectomy surgery had high mortality and post operative morbidity, The patients often developed postoperative respiratory distress, anastomosis leak.

Due to long post operative period and high morbidity, the patients were often depressed and needed psychiatric counseling.

So it was difficult to come for the final opinion regarding better treatment option in patients with carcinoma esophagus.

The low survival rate of the disease and morbidity , forced the treating physicians to look for better palliative procedures with less morbidity but at the same time improved the quality of life of patients.

For the palliation of disease Surgical treatment and the external beam radiotherapy were combinely done, and tried but it didn't improve the survival rate too. So all these surgical procedure were extra burden for the patients with short remaining life span. so the surgical treatments including bypass procedures were rarely done and simple palliative procedures were explored. So that the cardinal symptom dysphagia is relieved and , the patients can live their remaining life with improved quality of life.

Endoscpic palliation techniques:

The main aim of the palliation is dysphagia relief.

Endoscopic laser treatment:

This procedure was done by inserting a channel in to the growth and the tumour was destructed by heat produced by the LASER .The dysphagia improvement was better but the procedure is not simple ,It should be repeated for several weeks. so the use of LASER is now restricted to unblock the stent occlusion caused by the tumour over growth [2].

Esophageal stenting:

For the palliation of dysphagia, varieties of stents were tried , including the tubes of coiled silver wire known as the Souttar tube, rigid plastic tubes were tried for implantation . these procedures were done as endoscopic procedures.Later lot of research were done on stent palliation, thus the SEMS or self expanding metallic stents were developed which were easy to insert, with a little morbidity , avoided the general anesthesia ,surgically unfit and nutritionally poor patients were benefited , with improved dysphagia relief thus their health related quality of life also improved. The SEMS are initially in the collapsed state before the insertion, and it expands automatically after the insertion in side the lumen and it increased the width of the lumen very well ,thus improved dysphagia. [2]

Different types of Stents:

There are different types of esophageal stents available now[10],[21] ,like

- Plastic Stents
- Metallic Stents or SEMS

- Fully covered SEMS,
- partially covered SEMS,
- uncovered SEMS,

Fig 7.Types of Esophageal Stents.

The covered SEMS were useful in the setting of trachea esophageal fistula, the Meshed SEMS prevent the stent displacement . Placement of stents over the tumours that are more proximally located ,including the tumours near the cricopharyngeus, is poorly tolerated by the patients. The, stents placed over the the gastroesophageal junction are associated with complications including migration of the stents to the stomach they are also associated with the acid regurgitation.

Indications for stenting :

- Grade 3 or grade 4 dysphagia in any stage of carcinoma esophagus
- Dysphagia due to mucositis and stricture following radiotherapy ,or chemotherapy in carcinoma esophagus.
- Inoperable ,locally advanced or advanced carcinoma esophagus with cancer cachexia or nutritional deficiency, with severe dysphagia.

Esophageal dilation

It is a very simple procedure that can be useful in relieving dysphagia immediately but , the dilatation effect is only temporary which lasts for less than 30 days. Repeated dilations are often needed to maintain the effect, and the procedure is with its own complications too, including perforation.etc. due to its limitations the dilatation procedure is limited, and is mostly performed before the SEMS insertion procedure.

Other endoscopic methods:

The other palliative endoscopic procedures include bipolar diathermy, argon-beam plasma coagulation and injection of sclerosing agents like alcohol

Brachytherapy is another palliative treatment modality it is done by delivering radiation directly in the lumen or over the growth[13],[2]this is an expensive treatment modality . These methods are indicated for the patients with advanced carcinoma,

Among these palliative procedures the SEMS placement found to be simple cost effective and has less complications.

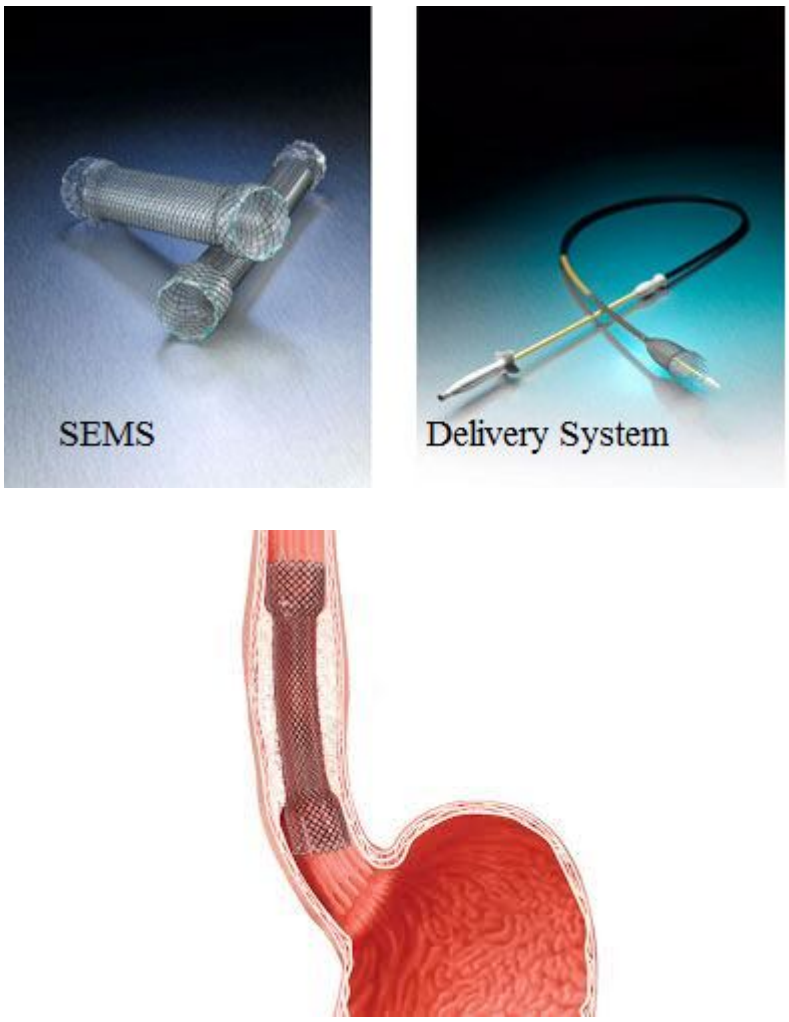
Self Expanding Metallic stent placement procedure:

SEMS or Self expandable metallic stents are devices, when placed across the narrowed or occluded lumen of esophagus they expand in width and keep the esophagus dilated, thus making way for easy passage of food

and water, SEMS are easy to insert and done as a day care procedure with minimum requirement of anesthesia, and it is well tolerated procedure, has less morbidity.

Placement of stents with meshed stents SEMS, the stents with metallic non injuring blunt barbed stents can decrease the incidence of migration of stent , and the use of stents which are coated with silicone or polyurethane prevent or delay tumor in growth and subsequent esophageal obstruction.

Fig. 8. SEMS and Delivery system.



Usually the SEMS placement is done by General Surgeons or Medical or Surgical Gastroenterologists in India. The SEMS can be placed as an out patient procedure but the patients are usually admitted prior to the procedure Placement of stents with metal mesh and barbs can reduce the migration of stent , The stents are now coated with silicone and polyurethane that can prevent and may be they delay tumor in growth and occlusion of esophagus is prevented.

Steps to prepare for the SEMS placement procedure:

- The patients are kept Nil By Mouth for 6 hours prior to the procedure, patients can drink water up to 2 hours before the procedure
- Patients are asked whether they are allergic to any medications or they have bronchial asthma
- Patients can take all their drugs as usual, except anticoagulants , like warfarin, Aspirin etc and they are advised to stop taking it before 5 days .

The procedure is explained in detail regarding its benefits ,complications to the patients and the written consent is obtained.

After getting the consent the patient is examined and the vitals are checked, local anesthetic spray is applied to the throat, and iv sedation is given if necessary.

The equipment contains

Upper GI endoscope,

Guide wire ,

Catheter with self expanding metallic stent.

First the endoscope is passed the narrowing are is visualized then the guide wire is passed beyond the narrowing caused by the tumour, then the catheter with SEMS is introduced then passed into the correct position across the blockage, after confirming the correct position catheter is released and removed after the SEMS is placed precisely in the correct location.

After self expanding esophageal stent placement, the people have an improvement in dysphagia.

As with any medical treatment, there may be some complications that can arise:

Minor complications:

- Slight bleeding may occur during the procedure, but this usually stops without any specific intervention .
- Mild or moderate pain while the stent ‘beds in’, that also usually settles within 24 hours to 72 hours
- Some patients get acid reflux afterwards and need antacid therapy for this.
- Rarely the stent may slip out of position. if it happens, patient may have to undergo repeat of the procedure.

Major complications

- ✓ Uncontrolled bleeding and
- ✓ Esophageal perforation occurs rarely

Food intake after esophageal stenting :

The will be able to start on fluids within a few hours. Patients are advised to have liquid diet for one or two days, after confirming the correct placement of the stent by X ray then soft solid diet is started

The stent is placed to relieve the dysphagia and allow the patient as normally as possible. But the physician should advise the patient not to forget the possibility of the stent getting blocked. The stents may get blocked if the food is not sufficiently chewed and swallowed or from the hard food particles that are difficult to break when chewed.

The following foods are difficult to break down, despite chewing, and may cause the stent to get blocked Fish bones, Tough gristly meat Hard boiled or fried egg , fruits like orange, pineapple, Raw vegetables and Stringy vegetables like , greens potato skins, salad leaves etc

To prevent the stent blocking the patients should take more time, relax and eat meals slowly.¬ Meals should be smaller than the patients are used to and patients should have more frequent food intake like five or six small meals rather than three big meals.

Cut the food into smaller pieces before eating normally take smaller mouthfuls and chew each mouthful very well. spit out the lumps that cannot be chewed well.

Take plenty of , gravy or cream ,curry with less spices and mix it with the meals. It makes the food moist, and become easier to swallow and pass through the stent.

Drink water frequently during and after meal it will help to keep the stent clear. Warm or carbonated drinks can be consumed and note that all fluids are beneficial. If the carbonated drinks worsen symptoms of heartburn or acid reflux. Sit upright at meal times and for one to two hours afterwards.

If the patients wear dentures, make sure to them fit correctly, so that food can be chewed well. Take the drugs in liquid form if possible or take them with plenty of fluids.

If the patients have poor appetite or they are losing weight, they will be advised to Eat small amounts but frequently, Choose full cream milk and full fat foods instead of low fat products if it is not contraindicated otherwise. Add sugar to cereals, puddings and beverages if the patients are non diabetic

If the patients are unable to maintain their weight, a dietitian advice may be sort or recommend some high calorie nutritious recipes or Potential problems associated stent

If the stent needs to be placed across the esophago gastric junction. An antacid therapy is needed, and the sleeping posture should not be too flat.

Prop up position up to a 30-45^0 angle will be useful .it can be done by using pillows or a bed spread. When the stent expands it can cause compression that leads to some pain , usually the pain subsides after 72 hours. Proper are used to control the pain.

The patients are advised to get reviewed If the dysphagia still persists despite the stent placement , because it may be due to the incorrect position of the stent or due to the stent migration,and the patients may need stent replacement.

Self Expanding Metallic stent placement procedure:

Fig .9 Obstruction due to carcinoma

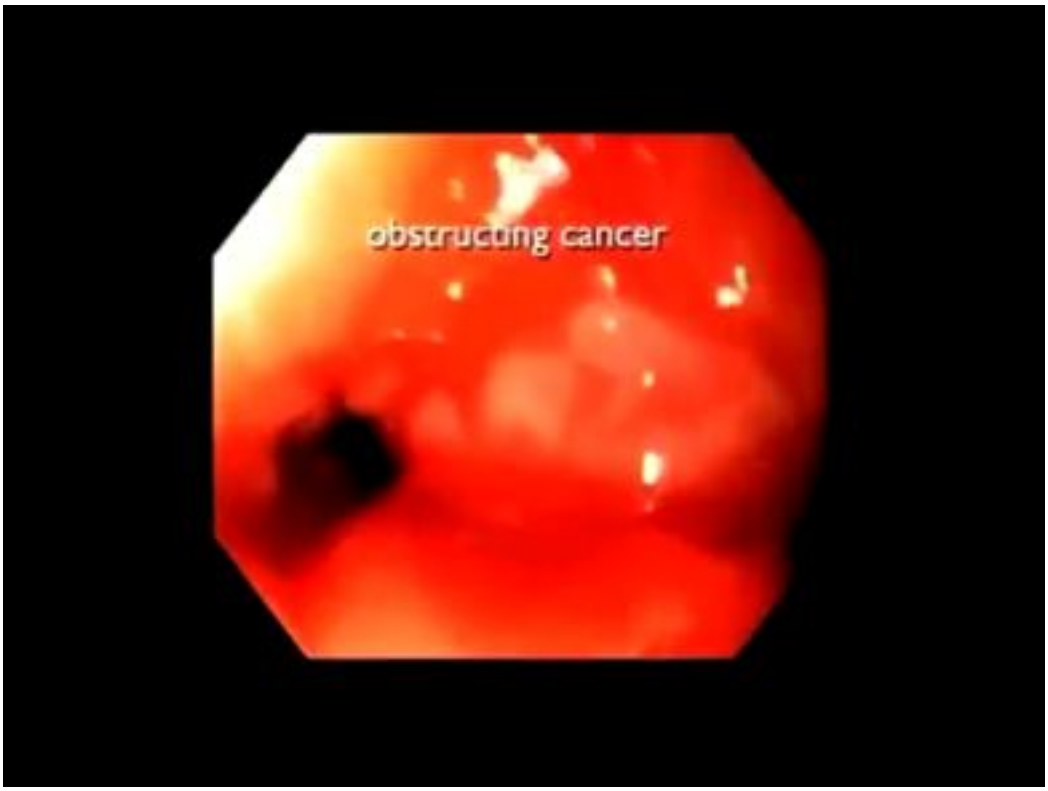


Fig 10.Guidewire passed through the tumour stricture

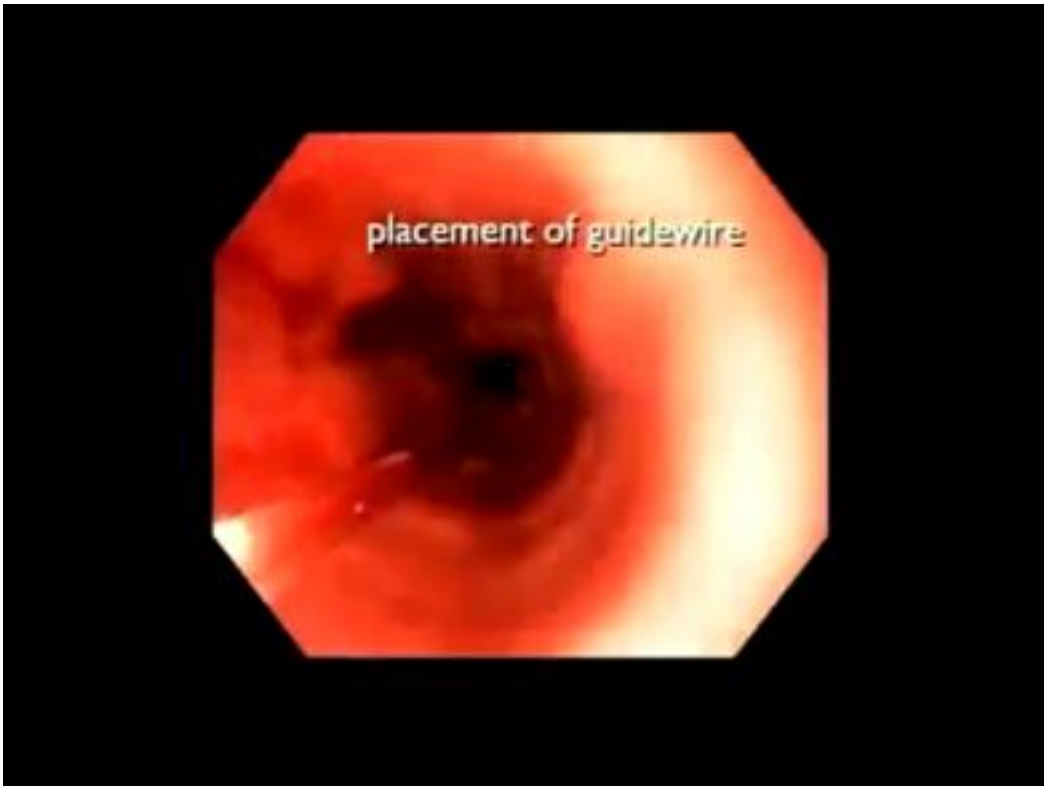


Fig 11Stent delivery system passed through the tumour stricture

Fig12 Stent placement done

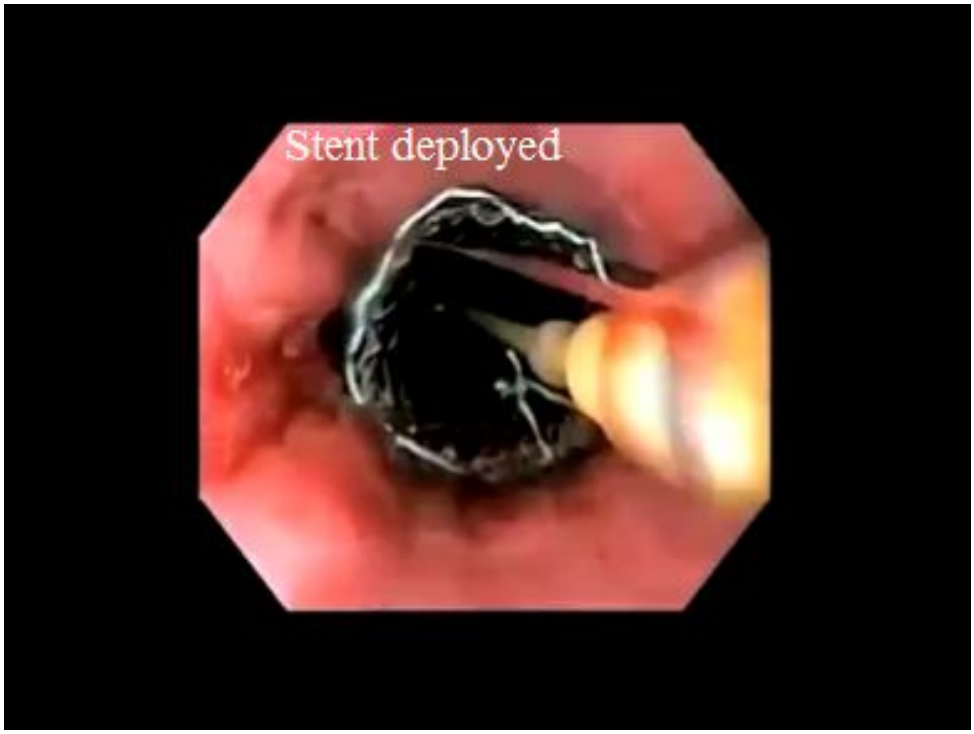


Fig 13.correction of position

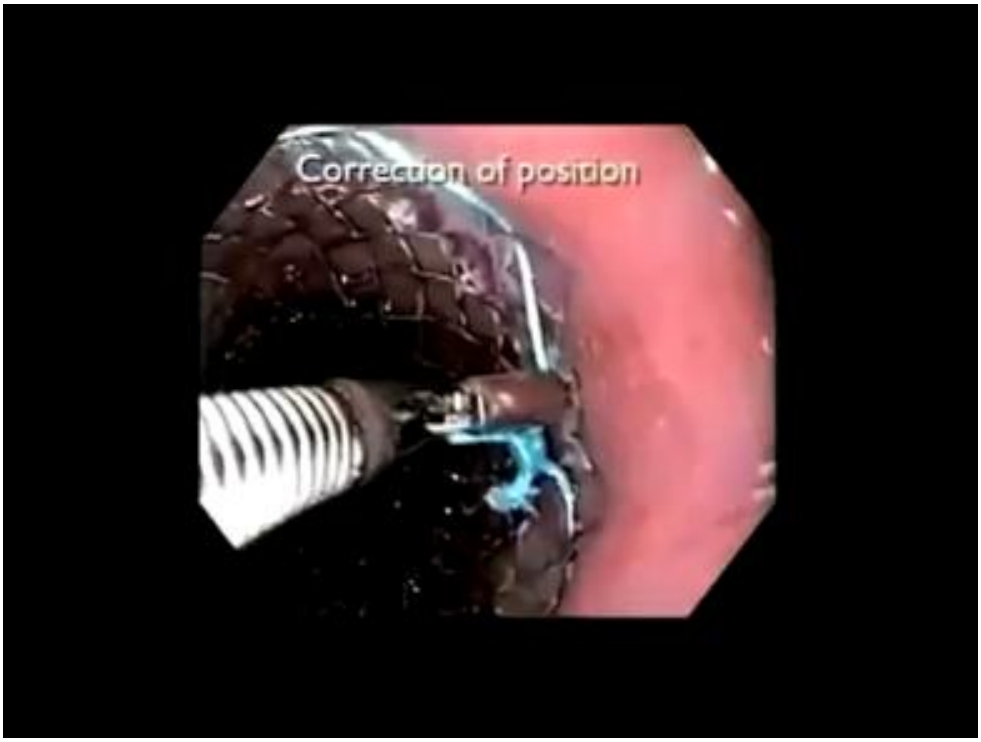


Fig 14.Final position after stent deployment.

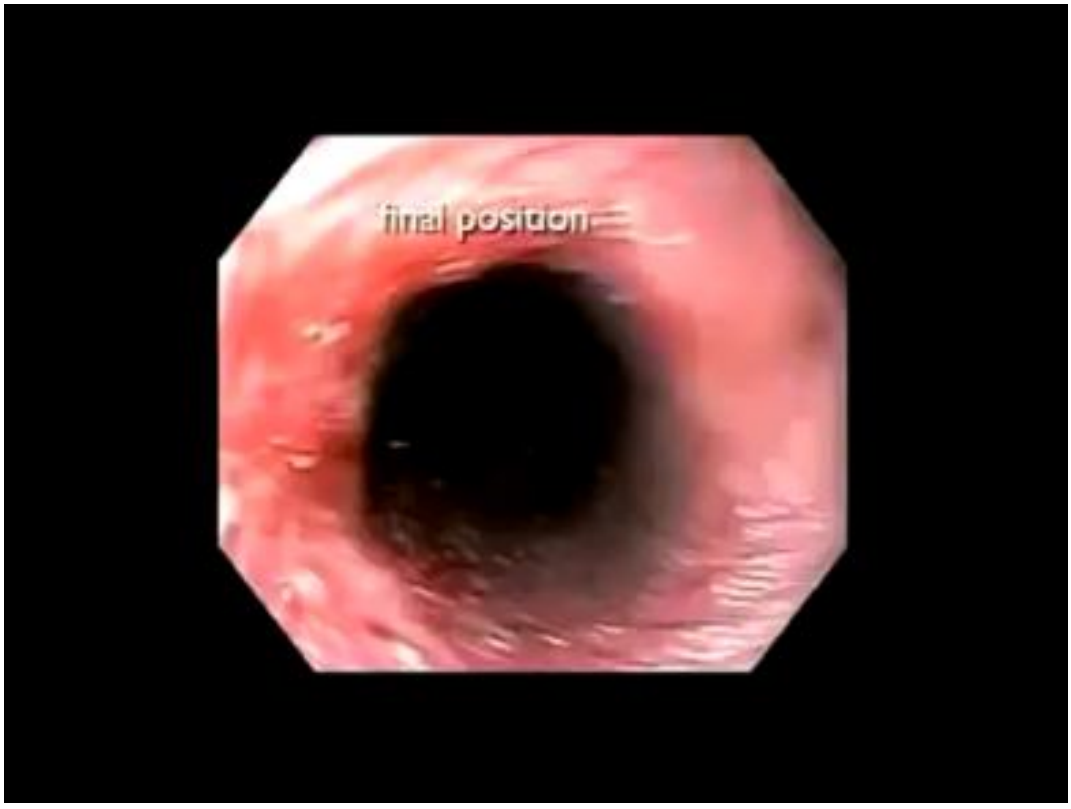


Fig 15.Stent after 0ne week and after 8 weeks.

Research and studies:

In our extensive search, we found that there are only limited studies were done evaluating the improvement of quality of life after esophageal stenting in patients with carcinoma esophagus ,most of the studies calculated the relief of dysphagia as the only indicator for the improvement of quality of life. The disease also has physical, emotional and social impacts on the life of patients, these parameters were not adequately considered.

Most of the studies focused only on relief of dysphagia ,and survival benefit of esophageal stenting, where as few studies compared the other palliative procedures with the esophageal stenting. Eg single dose radiation brachy therapy palliative treatment was compared with esophageal stenting,

Some studies compared other palliative procedures ,including PDT and cautery with the esophageal stenting.

Few studies focused on assessing improvement of quality considering the physical, emotional and social impacts on the life of patients , other anthropometrical, biochemical improvements were not adequately studied. In our study we tried to evaluate the health related improvement of quality of life (HRQOL) along with the improvement of anthropometrical, and biochemical improvement after stenting.

MATERIALS AND METHODS

The patients above 18 years of age with carcinoma of esophagus posted for esophageal stenting as per indications, who were willing to participate in the study after giving written informed consent, were studied over the period of one year between June 2014 to June 2015.

Study design:

This study is a prospective study.

Place of Study

The study was conducted in the department of General surgery and in the department of Gastroenterology, Govt Coimbatore Medical College Hospital, Coimbatore, after obtaining permission from The Heads of the concerned departments.

Sample size calculation:

The sample size required for this study was estimated with an assumption of statistical significance at 95% and power of study at 80% using the following formula:

$$n = 2 \times \{z\alpha + z\beta\}\ 2 \times \{SD\}^2 \ / \ \{Mcase - Mctrl\}^2$$

where

n = estimated sample size

$z\alpha = 1.96$ (at statistical significance of 95%)

$z\beta = 0.84$ (for a power of study at 80%)

SD = 10.3 Standard deviation[12] (reference no 12)

{Mcase- Mctrl} = 39effect size[12] (reference no 12)

M case =112

Mctrl = 73

Based on above calculation, the estimated sample size required for this study was around 2 cases[12] .

A total of 21 patients with a diagnosis of Carcinoma esophagus with grade 3 and grade 4 dysphagia who were posted and deployed covered Self expanding metallic stents were studied .

SELECTION CRITERIA

(a) Inclusion Criteria

- The patients above 18 years of age with carcinoma of esophagus posted for esophageal stenting as per indications, who are willing to participate in the study after giving written informed consent.

(b) Exclusion Criteria

- Pregnant women
- Persons not capable of giving consent (psychiatric patients)
- Persons unwilling to undergo the study (who refused to consent)

Statistical Tools:

The information and results collected from all the selected subjects were recorded in the Master Chart. Data analysis was done with the help of spss software version 19.5.

Using this software **Paired t test** , range, means, Standard deviations , and p values were calculated. A ‘p’ value less than 0.05 is taken to indicate the statistically significant relationship.

Ethical Clearance:

The study was conducted after getting prior permission from the department of Gastroenterology and General Surgery and the study proposal was approved in the ethics committee meeting conducted at Government Coimbatore Medical College, Coimbatore.

An informed consent was obtained from the subjects, both male and female patients with carcinoma of esophagus with dysphagia admitted in the IP departments of the Coimbatore Medical College Hospital, Coimbatore, Posted for the SEMS(self expanding metallic stents),placement, during the period of study (i.e. July 2014 to June 2015).

The type of stent used was covered self expandable metallic meshed stent, the same type was used for all the patients.

Pre-intervention assessment:

All subjects included in the study had undergone the following investigations and questionnaire based interview:

1. Quality of life was assessed with EORTC c30 OES 18 questionnaire
2. completehemogram,
3. absolute and differential blood cell counts,
4. Renal function test,

5. liver function test,
6. serum lipid profile,
7. blood sugar

The research includes interview of study subjects to collect data on socio demographic, disease and treatment related variables. The subjects were also underwent a detailed clinical examination. A questionnaire based enquiry of quality of life and psychomorbidity which was administered to all the subjects before the esophageal stenting which is a part of standard treatment protocol and

Post intervention assessment

All subjects were evaluated for improvement of quality of life with the EORTC C 30 OES 18 questionnaire, after the placement covered SEMS at the end of 1 week 4 weeks and 8 weeks after stenting respectively.

All subjects were evaluated with following standard laboratory tests at the end and 4 weeks and 8 weeks after placement of SEMS respectively.

1. completehemogram,
2. absolute and differential blood cell counts,
3. Renal function test,
4. liver function test,
5. serum lipid profile,
6. blood sugar

Methods

First the informed consent was obtained from the subjects to undergo the study, then the details were collected , including medical history and clinical examination of the subject, above mentioned lab investigations were done,

Assessment of Health related Quality of Life (HRQOL)

The health related quality of life was assessed with the questions based on translated Tamil version of EORTC QLQ –C30 .

The EORTC QLQ- OES 18 is a set of questionnaire developed by the European Organization for Research and Treatment of Cancer, to assess the quality of life of cancer patients. The questionnaire consists of total 18 questions first 4 four questions represent the dysphagia score .The response options each of the question are on a 4 point scale where 1 indicates maximum dysphagia and 4 indicates no dysphagia.

The questions are based on the following responses

1. Is the patient able to eat solid food? 1 2 3 4
2. Are the patients able to eat semi solid or soft food? 1 2 3 4
3. Are the patients able to you drink liquids? 1 2 3 4
4. Whether the patients able to swallow saliva?1 2 3 4

1 point for response Not at all , 2 points for A little ,3 points for Quite a bit, and 4 points given for, if the response to the question is Very much.

Questions from 7 to 15 represent the general health and social activities related quality of life, 4 points given to the response for each question indicates maximum impairment in quality of life, and the 1 point indicates no impairment.

7. whether patients had trouble with eating? 1 2 3 4
8. whether patients had trouble with eating in front of other people? 1 2 3 4
9. whether patients had a dry mouth? 1 2 3 4
10. whether patients had problems with your sense of taste? 1 2 3 4
11. whether patients had trouble with coughing? 1 2 3 4
12. whether patients had trouble with talking? 1 2 3 4
13. whether patients had acid indigestion or heartburn? 1 2 3 4
14. whether patients had trouble with acid or bile coming into their mouth?

The question items from 16 to 18 indicate the pain related quality of life the , 4 points were given for maximum pain perception response and 1 point for no pain perception. Thus the quality of life was measured in three categories.

15. whether patients had pain when they eat?
16. whether patients had pain in their chest?
17. whether patients had pain in their stomach?

The question items 5 and 6 were omitted due to ambiguity in points calculation .and not considered for calculation .

The subjects were evaluated by the above described methods before and at the end of the 1, 4and 8 weeks after stenting respectively . The results were analysed by **paired t test** and the p value was calculated with spss, 19.5 version software

SOURCE OF DATA

Data consists of primary data, collected by the principal investigator directly from the patients, who had approached the Government Medical College Hospital, Coimbatore and patients admitted as a inpatients in department of General Surgery, and Medical Gastroenterology.

RESULTS

General characteristics of study population.

Table 1:General characteristics of study population

Variables	N = 21
Age (in Years)	51.19 ± 8.37
Gender (male)	12 (57.1%)
BMI (Kgs/m^2)	20.63 $\pm$2.27
Tobacco smoking	12 (57.1%)
Tobacco chewing	8 (38.1%)
Alcohol intake	11 (52.4%)
Histopathological type Adenocarcinoma Squamous cell carcinoma	 10 (47.6%) 11 (52.4%)
Location of tumour Mid third of esophagus Lower third of esophagus	 11 (52.4%) 10 (47.6%)
Stage of cancer Stage III Stage IV	 17 (81.0%) 4 (19.0%)
Dysphagia Grade Grade3 Grade4	16(76.2%) 5(23.8%)

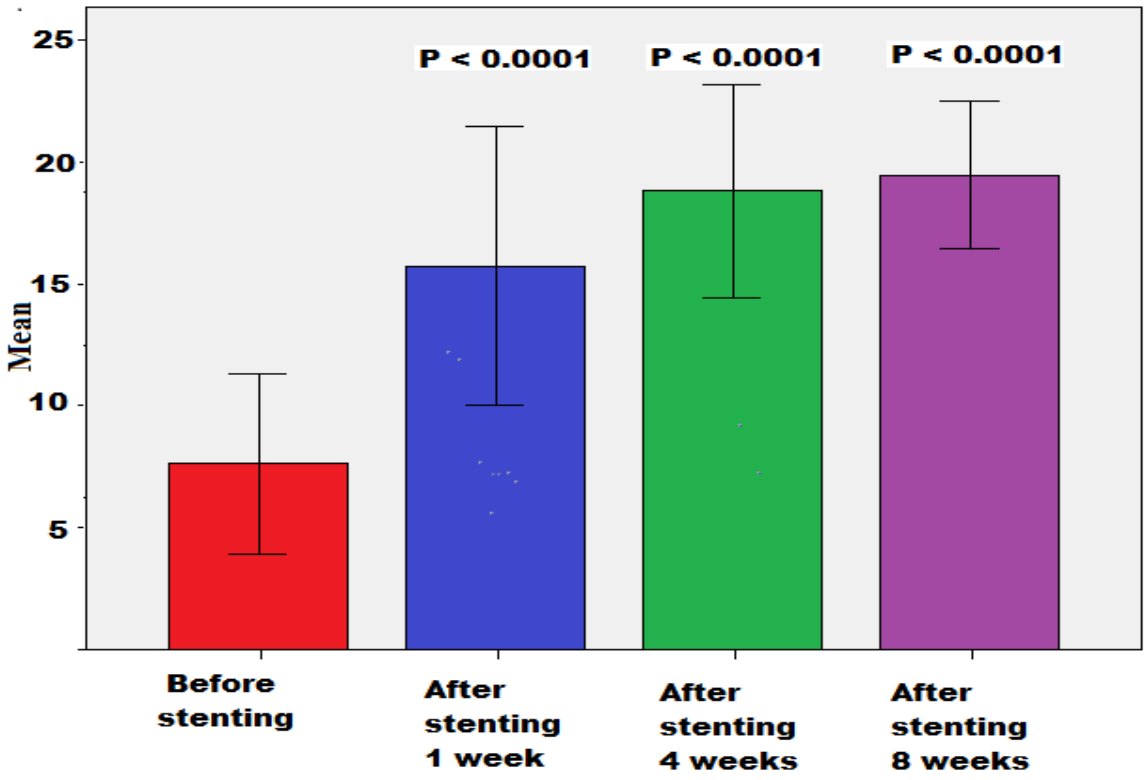
Total 21subjects were studied.

- There were 12 males (57.1%) and 19 females (42.9%).
- The Age of the patients ranged from 45 years to 73 years with a mean ± SD of 51.19± 8.37.
- Sixteen patients were with
- The BMI of the patients ranged from to with a mean ±SD of 20.63±2.27.
- The number of patients who smoked tobacco were 12 (57%) and chewed tobacco were 8(38.1%) .
- Alcohol consumption was noted in 11 patients (52.4%)
- The histopathologictype, the total number of adenocarcinoma were 10(47.6%), and the number of squamous cell carcinoma were 11 (52.4%).
- In 11(52.4%) patients the tumour was located in the middle third and 1047.6%) patients had tumour in the lower third of esophagus
- The number of patients with Stage 3 disease with severe dysphagia were 17 (81%) and stage 4 disease were 4(19%) .
- Four Patients (19%) were with comorbid condition diabetes mellitus and patient were with Hypertension .
- Twenty patients(95.2%)were from urban area ,and only one patient (4.76%) was from rural area .
- There was stent migration observed in one patient (4.76%) 4 days after stenting for which reinsertion was done.

Table 2 , The symptom burden and global health of subjects before and after stenting.

variables	Before stenting	One week after stenting Comparison	Four weeks after stenting	Eight weeks after stenting
Dysphagia score	6.10 ± 1.48	12.57 ± 2.29	15.05 ± 1.74	15.57 ±1.74
Pain Score	7.10 ± 1.54	10.00±1.97	5.38±1.53	4.00±0.95
Global health score	32.45 ± 2.24	26.33±3.56	15.05±2.22	13.14±1.98

Chart 1: Comparison of dysphagia score before and after stenting for esophageal cancer. The bars represent the mean score of Dysphagia and the error bar indicates standard deviation. P value gives statistical significance of association of 'after stenting' scores with 'before stenting' scores of dysphagia.



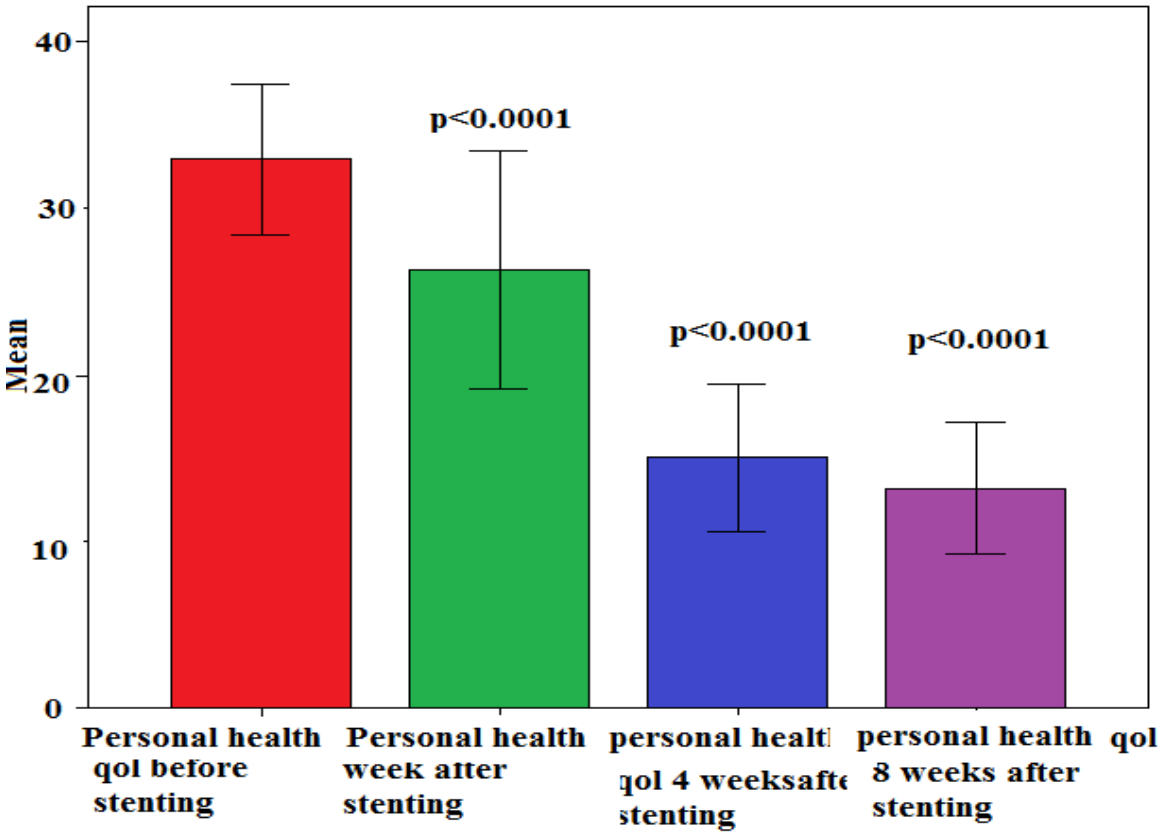
The improvement of dysphagia to solids and liquids improved significantly after stenting ($p<0.0001$)

Table3: Comparison of dysphagia score before and after stenting using paired t test.

Timelines in relation to stenting	Mean + SD	Mean difference + SD (compared with score before stenting)	P value
Before stenting	6.10 ± 1.48	-	
One week after stenting	12.57 ± 2.29	6.47 ± 2.44	< 0.0001
Four week after stenting	15.05 ± 1.74	8.95 ± 2.57	< 0.0001
Eight weeks after stenting	15.57 ± 1.20	9.47±1.83	< 0.0001

The improvement of dysphagia to solids and liquids improved significantly after stenting ($p<0.0001$)

Chart 2.Comparison of personal health related quality of life score before and after stenting for esophageal cancer. The bars represent the mean score of personal health related quality of life and the error bar indicates standard deviation. P value gives statistical significance of association of 'after stenting' scores with 'before stenting' scores of personal health related quality of life .



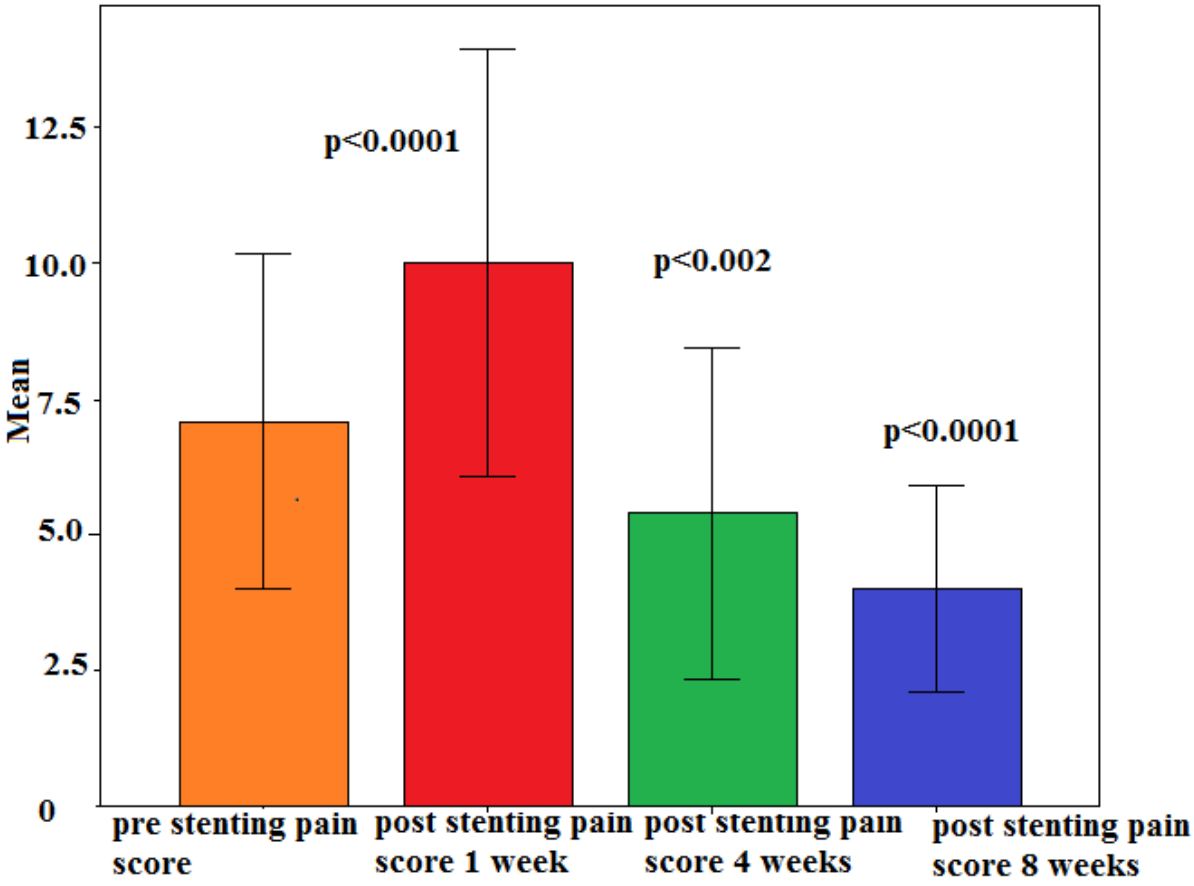
The Improvement in personal health related Quality of life after stenting is statistically significant.(P<0.0001)

Table 4: Comparison of Personal health related QOL score before and after stenting using paired t test

Timelines in relation to stenting	Mean ± SD	Mean difference ± SD (compared with score before stenting)	P value
Before stenting	32.95±2.24	-	
One week after stenting	26.33±3.56	6.61±3.98	P<0.0001
Four weeks after stenting	15.05±2.22	17.90±2.98	P<0.0001
Eight weeks after stenting	13.14±1.98	19.81±2.37	P<0.0001

The Improvement in personal health related Quality of life after stenting is statistically significant.(P<0.0001)

Chart 3: Comparison of pain score before and after stenting for esophageal cancer. The bars represent the mean score of Pain and the error bar indicates standard deviation. P value gives statistical significance of association of 'after stenting' scores with 'before stenting' scores of Pain related quality of life.



The Pain increases up to one week significantly($p<0.0001$) after stenting and then it decreases significantly at 4^{th} and 8^{th} weeks,($P<0.002$) and($P<0.0001$) respectively.

Table 5: Comparison of pain score before and after stenting using paired t test.

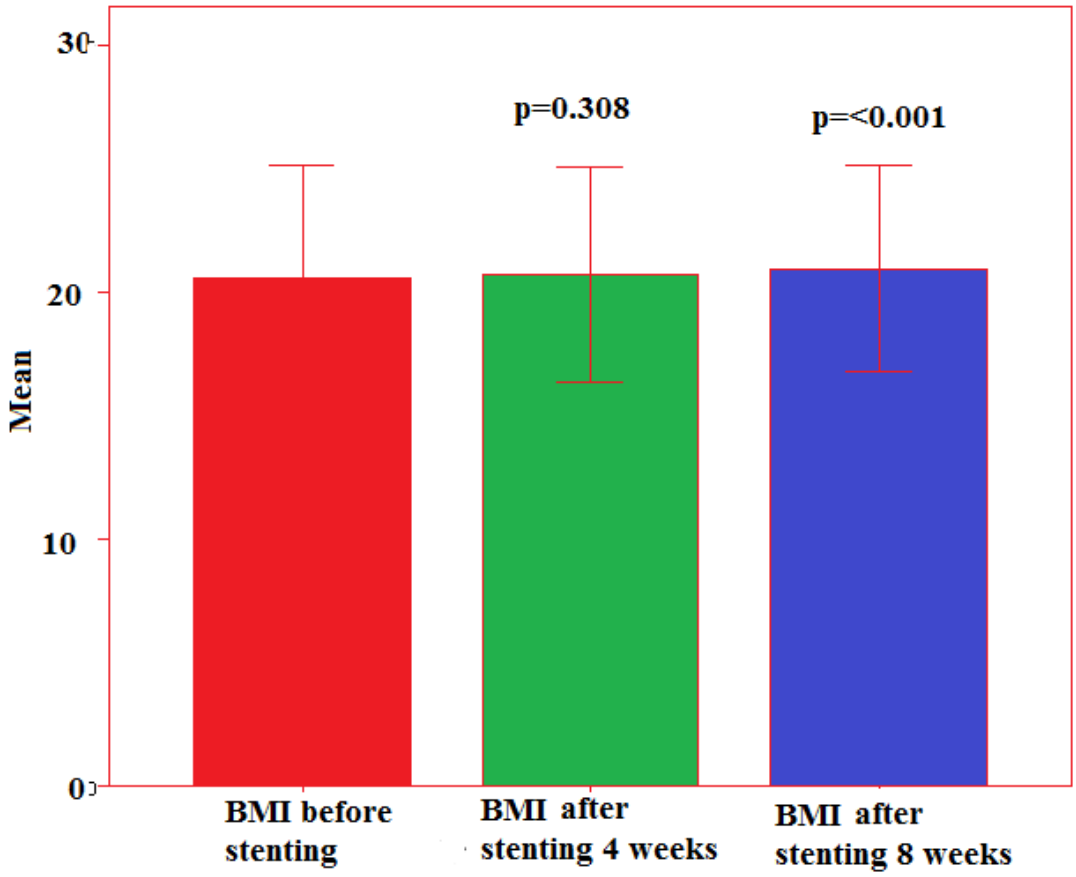
Timelines in relation to stenting	Mean + SD	Mean difference + SD (compared with score before stenting)	P value
Before stenting	7.10±1.54	-	-
One week after stenting	10.00±1.97	2.290±2.42	P<0.0001
Four week after stenting	5.38±1.53	1.714±2.26	P<0.002
Eight weeks after stenting	4.00±0.95	3.09±1.64	P<0.0001

The Pain increases up to one week significantly($p<0.0001$) after stenting and then it decreases significantly at 4^{th} and 8^{th} weeks,($P<0.002$) and($P<0.0001$) respectively.

Table 6.,Comparison of anthropometric and biochemical variables in subjects before and after stenting.

variables	Before stenting	Four week after stenting	Eight weeks after stenting
BMI (kgs / height m^2)	20.63±2.28	20.73±2.16	20.99±2.10
Hemoglobin g/dl	10.53±1.48	10.54±1.35	10.95±1.37
Blood sugar mg/dl	125.67±63.24	114.1±42.4	119±25.38
Blood urea mg/dl	37.86±9.45	37.14±7.76	32.86±6.14
Serum Creatinine mg/dl	1.074±0.28	1.019±0.28	0.995±0.20
Total proteins g/dl	5.92±0.78	6.25±0.67	6.47±0.58
Serum albumin g/dl	3.63±0.5	3.89±0.32	4.06±0.43
Serum globulin g/dl	2.28±0.49	2.35±0.43	2.41±0.59
Total bilirubin mg/dl	0.86±0.19	0.93±O.21	1.65±2.28
SGOT , IU/L	36.29±6.2	33.24+4.9	39.52+4.79
SGPT , IU/L	33.33±6.32	36.90+12.31	44.81+6.78

Chart 4 : Comparison of BMI score before and after stenting for esophageal cancer. The bars represent the mean score of BMI and the error bar indicates standard deviation. P value gives statistical significance of association of 'after stenting' scores with 'before stenting' scores of BMI.



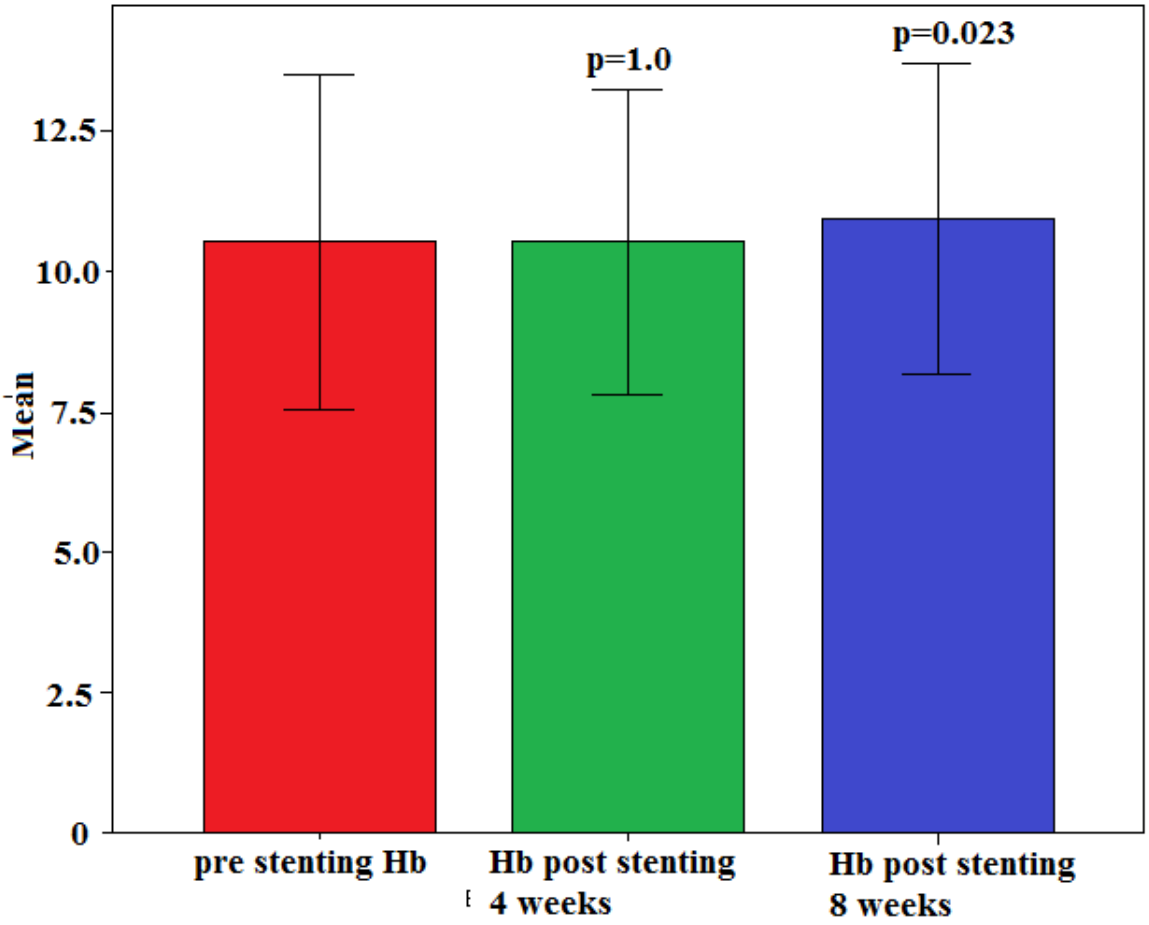
The improvement of BMI is non significant 4 weeks after stenting, but it is statistically significant after 8 weeks.(p=0.308) and (p<0.001) respectively.

Table, 7 Comparison of BMI before and after stenting

Timelines in relation to stenting	Mean + SD	Mean difference + SD	P value
Before stenting BMI	20.63+2.28	-	-
BMI 4 weeks after stenting	20.73+2.16	0.09+0.38	0.0281
BMI 8 weeks after stenting	20.99+2.10	0.36+0.6	0.072

The improvement of BMI is non significant 4 weeks after stenting, but it is statistically significant after 8 weeks.($p=0.308$) and ($p<0.001$) respectively

Chart 5: .Comparison of Hemoglobin score before and after stenting for esophageal cancer. The bars represent the mean score of Hemoglobin and the error bar indicates standard deviation. P value gives statistical significance of association of 'after stenting' scores with 'before stenting' scores of Hemoglobin.



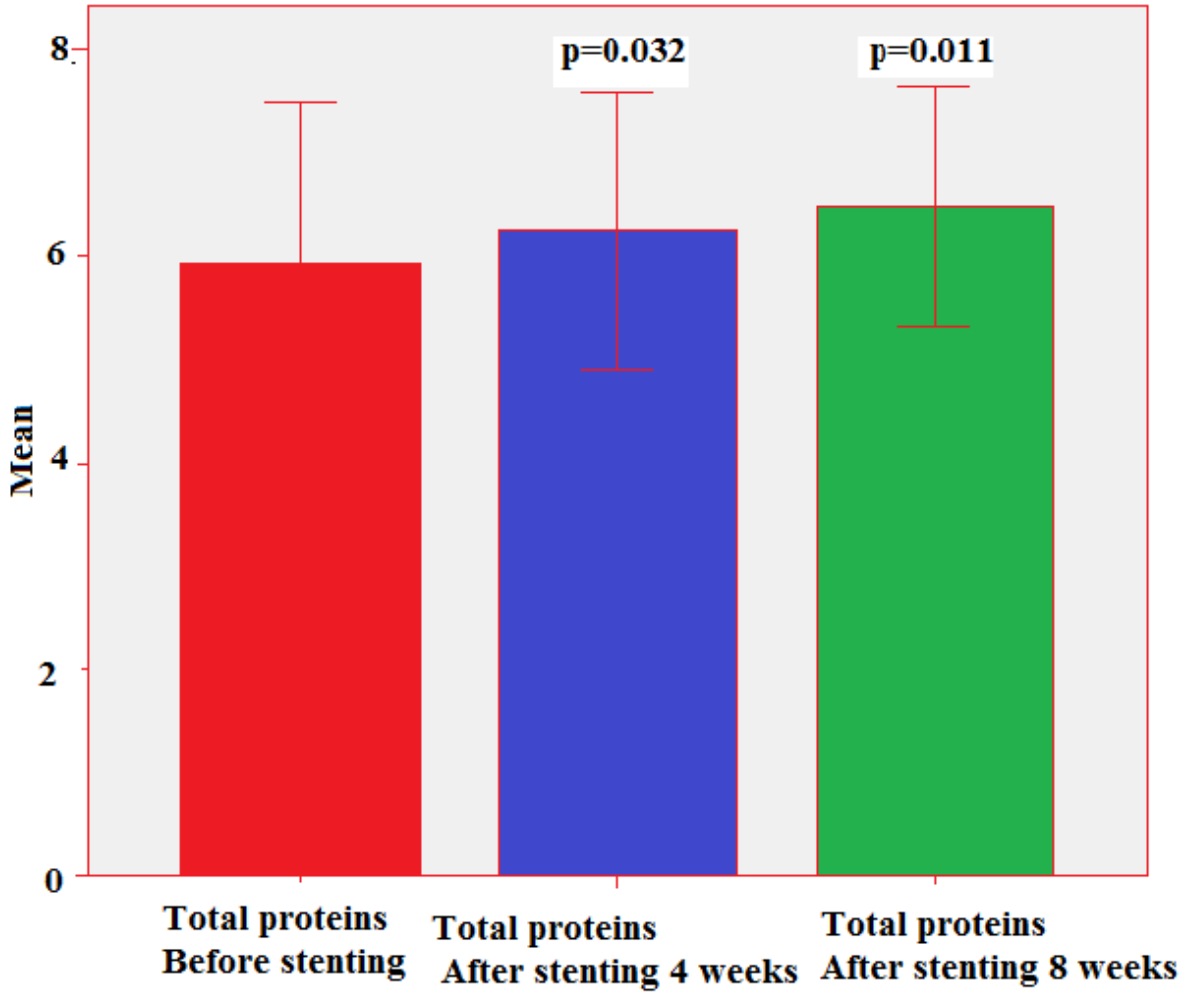
The improvement of Hemoglobin level is non significant 4 weeks after stenting but it is statistically significant 8 weeks after stenting.(p=1) and (p=0.023) respectively.

Table 8 Comparison of Hemoglobin before and after stenting

Timelines in relation to stenting	**Mean + SD**	**Mean difference + SD**	**P value**
Before stenting Hb	10.53+1.48	-	-
4 weeks after stenting Hb	10.53+1.35	0.00+0.58	1.00
8weeks after stenting Hb	10.95+1.37	0.41+o.77	0.023

The improvement of Hemoglobin level is non significant 4 weeks after stenting but it is statistically significant 8 weeks after stenting.(p=1) and (p=0.023) respectively.

Chart 6 : Comparison of Total protein score before and after stenting for esophageal cancer. The bars represent the mean score of Total proteins and the error bar indicates standard deviation. P value gives statistical significance of association of 'after stenting' scores with 'before stenting' scores of Total proteins.



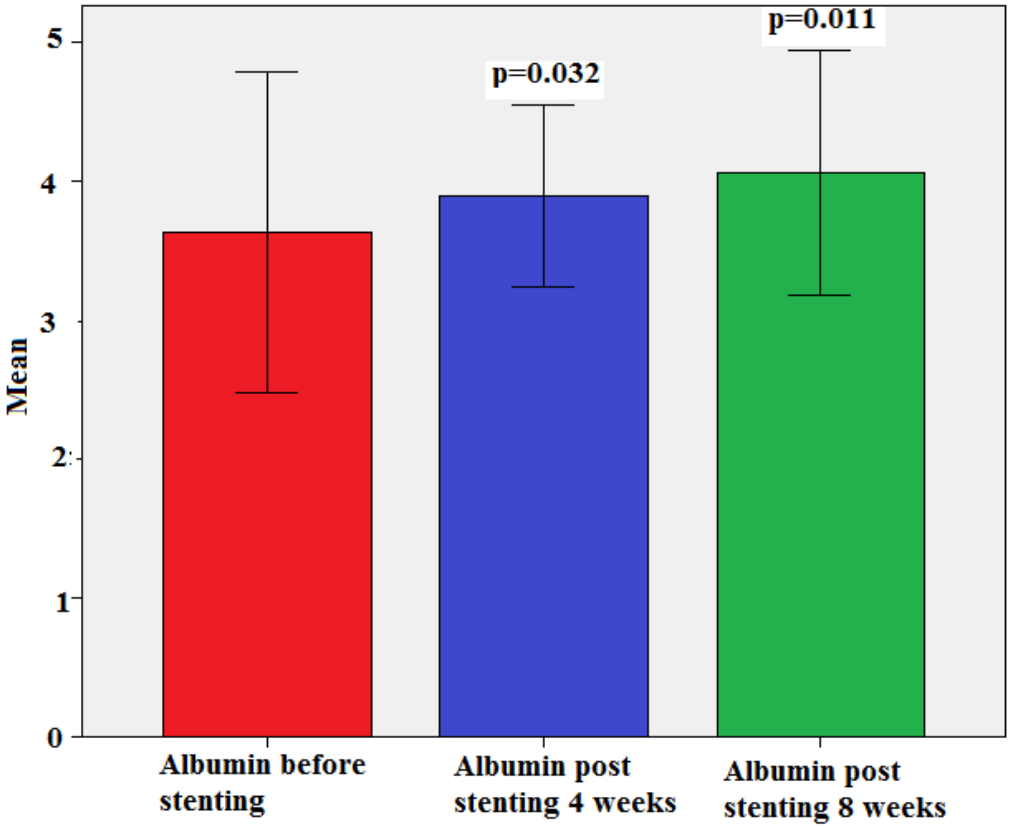
The improvement of Total proteins is statistically significant after 4 weeks and 8 after stenting.(p=0.032) and (p=0.011) respectively.

Table 9.Comparison of Total protein score before and after stenting for esophageal cancer.

Timelines in relation to stenting	Mean + SD	Mean difference + SD	P value
Before stenting	**5.92+0.78**	**-**	**-**
After 4 weeks	**6.26+0.67**	**0.32+0.72**	**0.051**
After 8 weeks	**6.47+0.58**	**0.553+0.88**	**0.01**

The improvement of Total proteins is statistically significant after 4 weeks and 8 after stenting.(p=0.032) and (p=0.011) respectively.

Chart 7 : Comparison of Albumin score before and after stenting for esophageal cancer. The bars represent the mean score of Albumin and the error bar indicates standard deviation. P value gives statistical significance of association of 'after stenting' scores with 'before stenting' scores of Albumin.



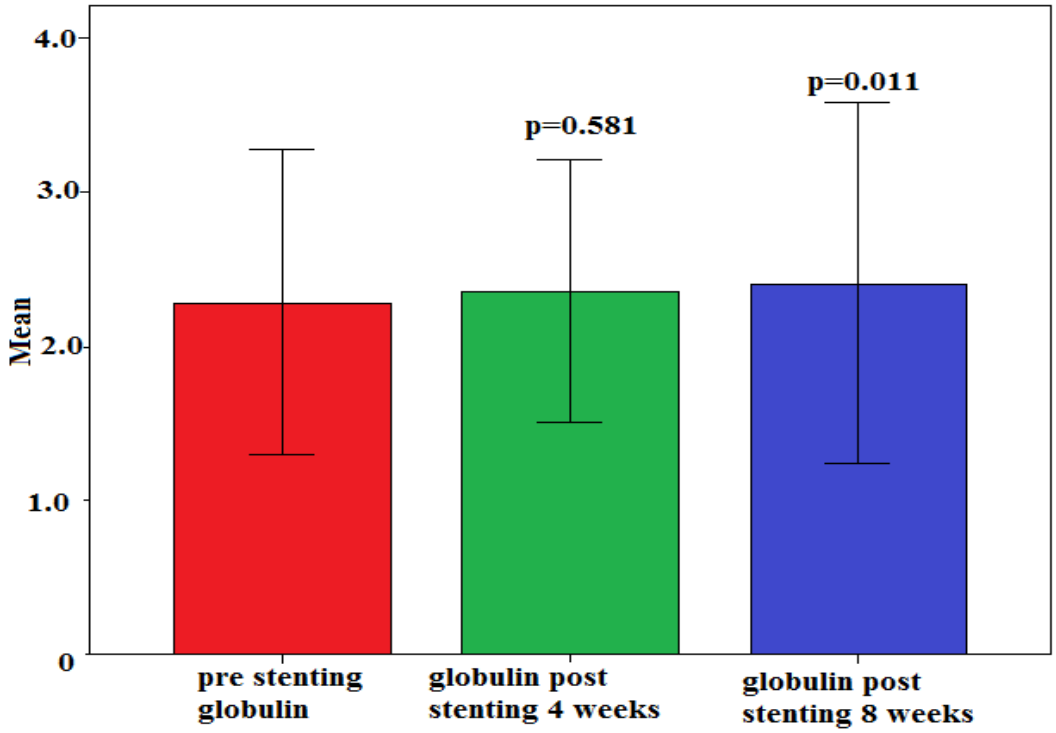
The improvement of Albumin level is statistically significant after 4 weeks and 8 weeks after stenting.

Table,10: Comparison of Albumin before and after stenting

Timelines in relation to stenting	Mean + SD	Mean difference + SD	P value
Before stenting	3.63+0.57	-	-
After 4 weeks	3.89+0.32	0.25+0.51	0.32
After 8 weeks	4.06+0.43	0.43+0.69	0.011

The improvement of Albumin level is statistically significant after 4 weeks and 8 weeks after stenting.

Chart 8: Comparison of Globulin score before and after stenting for esophageal cancer. The bars represent the mean score of Globulin and the error bar indicates standard deviation. P value gives statistical significance of association of 'after stenting' scores with 'before stenting' scores of Globulin.



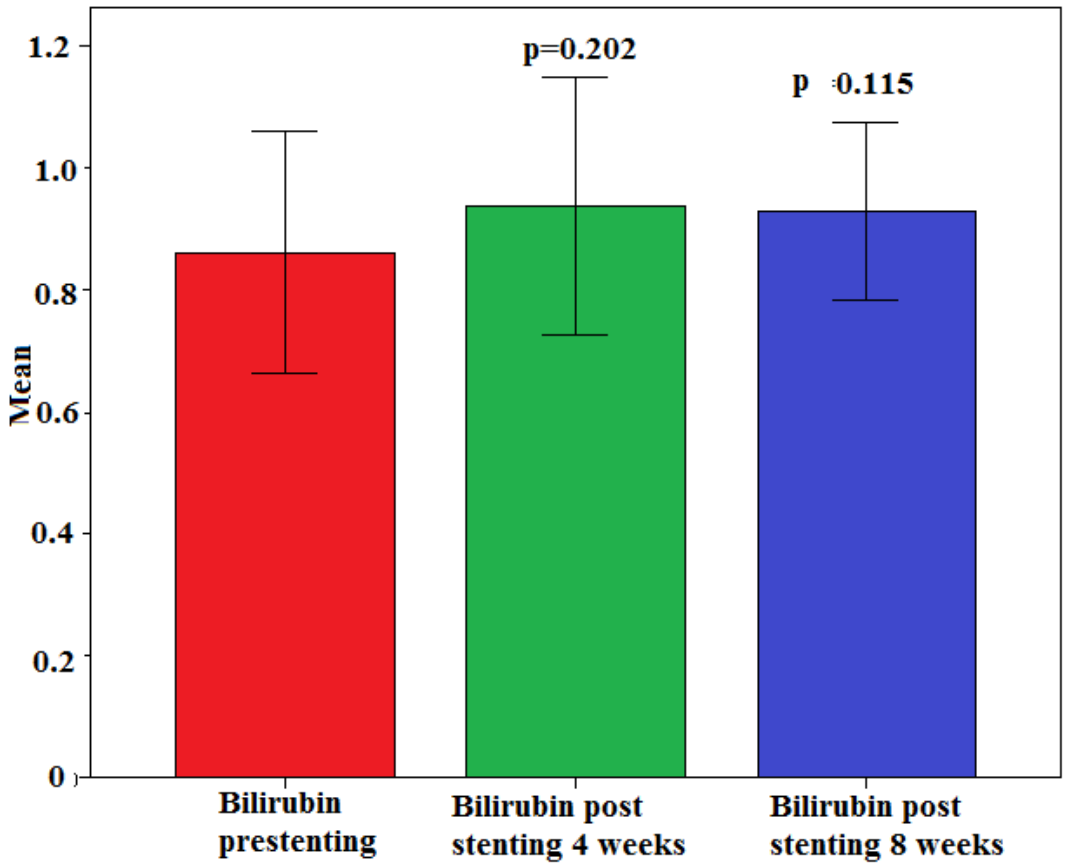
The improvement of globulin level is non significant statistically after 4 weeks but the improvement is significant 8 weeks after stenting.

Table,11:Comparison of Globulin before and after stenting

Timelines in relation to stenting	Mean + SD	Mean difference + SD	P value
Before stenting	2.28+0.49	-	-
After 4 weeks	2.35+0.43	0.071+0.58	0.581
After 8 weeks	2.41+0.59	0.127	0.77

The improvement of globulin level is non significant statistically after 4 weeks but the improvement is significant 8 weeks after stenting.

Chart 9 : Comparison of Total Bilirubin score before and after stenting for esophageal cancer. The bars represent the mean score of Total Bilirubin and the error bar indicates standard deviation. P value gives statistical significance of association of 'after stenting' scores with 'before stenting' scores of Total Bilirubin.



The Change in the bilirubin levels before stenting 4 and 8 weeks after stenting is statistically not significant.

P= 0.202 and P = 0.115 respectively

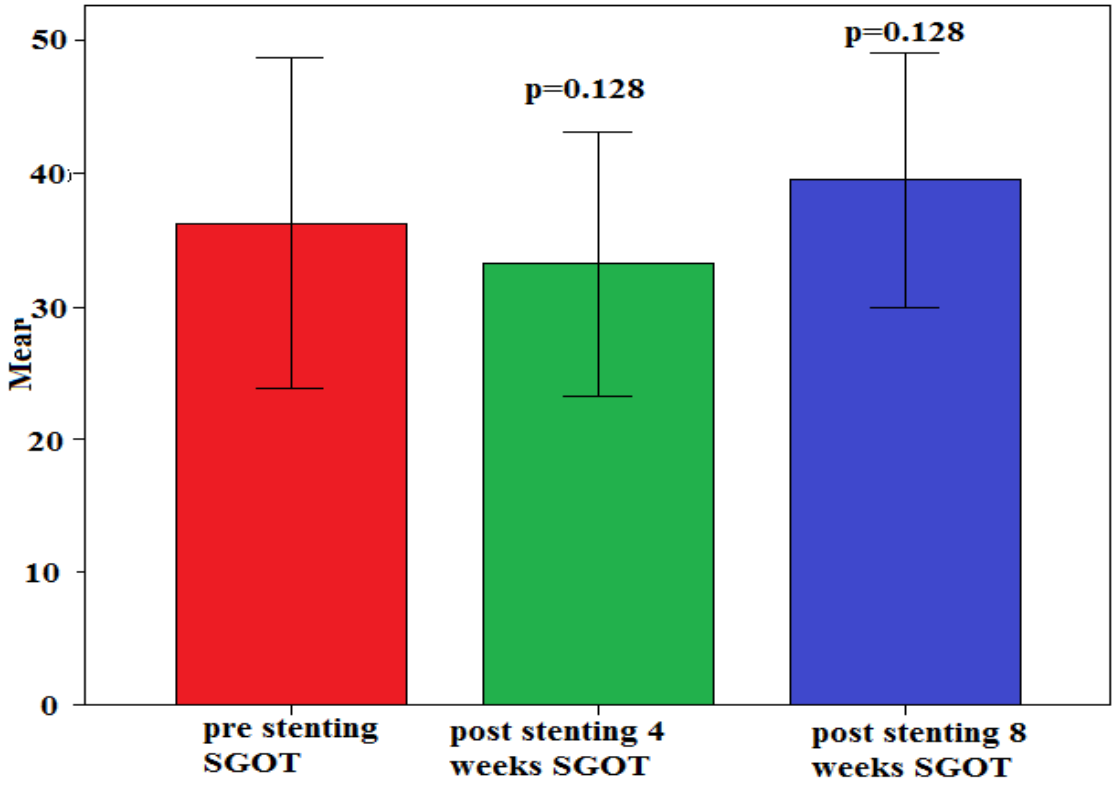
Table.12 Comparison of Total Bilirubin before and after stenting

Timelines in relation to stenting	Mean + SD	Mean difference + SD	P value
Before stenting	0.86+0.19	-	-
After 4 weeks	0.93+0.21	0.07+0.26	0.202
After 8 weeks	1.65+2.28	0.79+2.21	0.115

The Change in the bilirubin levels before stenting 4 and 8 weeks after stenting is statistically not significant.

P= 0.202 and P = 0.115 respectively

Chart 10 : Comparison of SGOT score before and after stenting for esophageal cancer. The bars represent the mean score of SGOT and the error bar indicates standard deviation. P value gives statistical significance of association of 'after stenting' scores with 'before stenting' scores of SGOT.



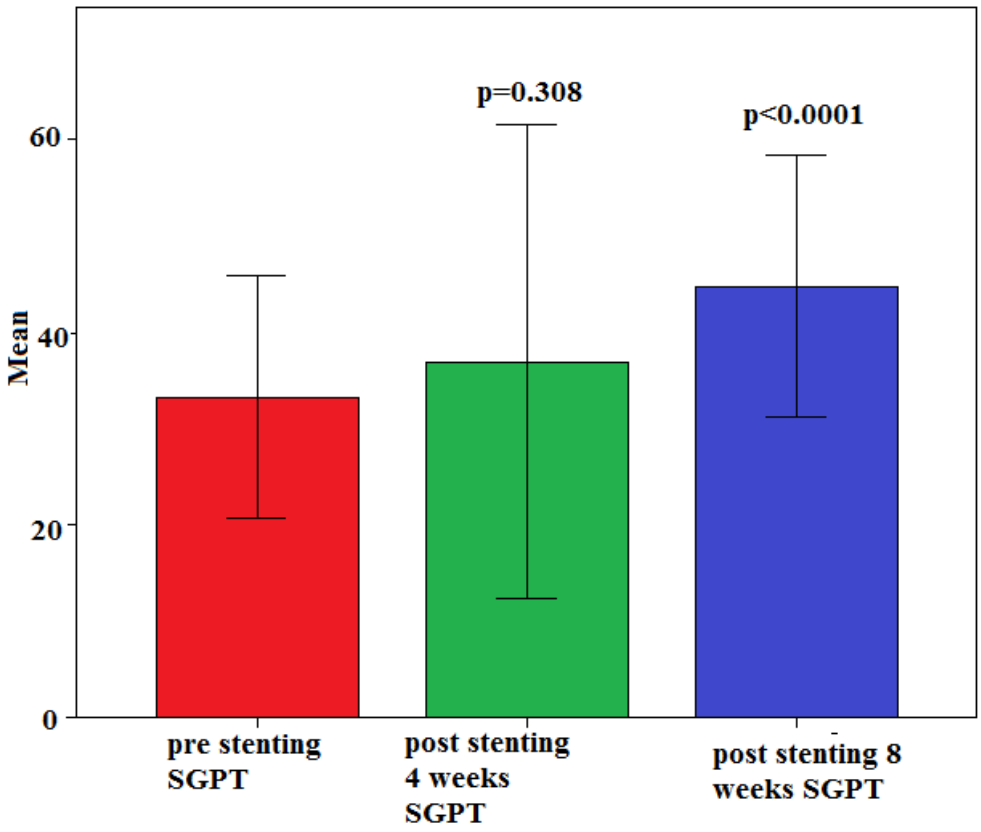
The change in the SGOT levels are statistically non significant after 4 weeks and 8 weeks after stenting.

Table,13:Comparison of SGOT before and after stenting

Timelines in relation to stenting	Mean + SD	Mean difference + SD	P value
Before stenting	36.29+6.2	-	-
After 4 weeks	33.24+4.9	3.05+8.8	0.128
After 8 weeks	39.52+4.79	3.23+9.35	0.128

The change in the SGOT levels are statistically non significant after 4 weeks and 8 weeks after stenting.

Chart 11 : Comparison of SGPTscore before and after stenting for esophageal cancer. The bars represent the mean score of SGPT and the error bar indicates standard deviation. P value gives statistical significance of association of 'after stenting' scores with 'before stenting' scores of SGPT.



The increase in SGPT levels after stenting is non significant after 4 weeks but it is significant after 8 weeks post stenting.

Table,14: Comparison of SGPT before and after stenting

Timelines in relation to stenting	Mean + SD	Mean difference + SD	P value
Before stenting	33.33	-	-
After 4 weeks	36.90+12.31	3.57+15.64	0.308
After 8 weeks	44.81+6.78	11.47+7.11	<0.0001

The increase in SGPT levels after stenting is non significant after 4 weeks but it is significant after 8 weeks post stenting.

DISCUSSION

In studies conducted all over the world by comparing the quality of life of patients with carcinoma esophagus before and after esophageal stenting, The success rate of the stenting procedure was around 80-95%, in most of the studies[27,].

In our study also the procedural success rate was around 95%out of 21 patients only one patient had the complication of stent migration, which needed reinsertion.

A prospective study conducted in the AIIMS, New Delhi, Madusudhan et al[3].studied the improvement of quality of life after esophageal stenting in carcinoma esophagus , 33 patients were studied before and after stenting, the results were published in the year 2009.In that study improvement of quality of life after stenting was assessed with EORTC QLQ 30 OES 18 (version 3). The results were in favour of esophageal stenting as a palliative procedure, because the improvement of quality of life was statistically significant .

In another study conducted byNanda Kishore Maroju et al[11], in the department of Surgery ,JIPMER ,Pondichery. 29 patients were deployed covered SEMS for malignant dysphagia in the year between 2001 -2003 , in the result though there was increase in pain scores ,all patients had significant relief of dysphagia and improvement in quality of life,

In our study also, we observed similar results, like the dysphagia relief is immediate and statistically significant, after stenting . The pain score initially got worsened after stenting but later it showed improvement. The general health score also improved following stenting, the improvement in score were also statistically significant.

A retrospective study conducted in Ataturk University[12],Turkey, 170 patients treated with palliative esophageal stenting from the year 2000 to 2008 The improvement of dysphagia was evaluated by modified Takita's grading system that improved from 3.4 before the procedure to 2.6 after stenting , it also concludes that stenting require less frequent intervention after stenting, and provides significant improvement in dysphagia and quality of life .

Sahlgrenska University Hospital [13] conducted a randomized controlled clinical trial in total of 65 patients, out of which 34 patients underwent SEMS insertion and the remaining 31 were treated with endoluminal brachytherapy , the results were published in the year 2005, the improvement of dysphagia was measured with EORTC QLQ 30 OES 23 questionnaire. Statistically Significant improvement was noted in the SEMS group. In our study also, the dysphagia relief is significant after 7 days, 4weeks and 8 weeks respectively .

Another study conducted by Martin et al [8] compared the results of esophageal stenting Vs.endoscopic esophageal dilatation procedures. A Total of 18 patients underwent stent insertion and 24 patients were treated only with endoscopic dilatation strictures. The results were also in favour of esophageal stenting. It concluded that the use of a SEPS was safe, not only the dysphagia relief is significant, but also economically beneficial and cost effective ,compared with the failed or multiple dilatation procedures. But Cochrane Database ,Interventions for dysphagia in oesophageal cancer. Dai Y1, Li C,et al[7], concluded that SEMS are safer and more effective than plastic stents.

In our study, the relief of dysphagia , general health related improvement of quality of life, and pain related improvement of quality of life were studied with the help of EORTC QLQ 30 OES 18 questionnaire, in addition to this we have studied and compared the anthropometric improvement like BMI, Biochemical improvement like, Hemoglobin ,Total proteins ,and other liver function tests, SGOT,SGPT , before and after stenting.

The dysphagia score is 6.10$\pm$1.48 before stenting ,it improved to 12.57$\pm$2.29 after 1 week,15.05$\pm$1.74,after 4 weeks and 15.57 $\pm$1.20 after 8 weeks. Thus the improvement of dysphagia before and after stenting is statistically significant.

The personal social health related quality of life score before stenting was 32.95±2.24, it improved to 26.33±3.56, after one week ,15.05±2.22 after 4 weeks and 13.14±1.98 after 8 weeks. The improvement of health related quality of life is also statistically significant.

The pain related quality of life was 7.10±1.54 before stenting, after one week the pain got worsened and it increased to 10.00±1.97 .The worsening of pain after one week is statistically significant.After 4 weeks the pain related quality of life improved from the baseline score before stenting to 5.38,and after 8 weeks it further improved to 4.00±0.95,These improvements in pain related quality of life too are statistically significant.

The improvement of BMI and Hemoglobin 4 weeks after stenting is statistically not significant , but 8 weeks after stenting , the improvement of BMI and hemoglobin are statistically significant

The biochemical parameters like Blood sugar, Urea are within the normal limits except for the diabetic patients, but the variation is statistically significant , before Vs 4 weeks and 8 weeks after stenting.

The variation in the creatinine values before and after stenting is not significant.

A statistically significant improvement is noted in the values of the total proteins and albumin measured at 4 weeks and 8 weeks post stenting, whereas the globulin improvement became significant only after 8 weeks.

No statistically significant changes are noted in the values of liver function tests like total bilirubin and SGOT, but SGPT values are found to be increased with statistically significant values, 8 weeks after stenting, due to unexplained reasons.

CONCLUSION:

- There is a definite and statistically significant improvement in the relief of dysphagia after esophageal stenting in carcinoma esophagus .
- There is a significant improvement in the personal, social health related quality of life, after the esophageal stenting in carcinoma esophagus.
- There is an initial deterioration of pain score at the first week ,then followed by statistically significant improvement in the pain related quality of life after stenting, in carcinoma esophagus.
- Though there is improvement in the anthropometrical (BMI) score after stenting, the improvement is statistically non significant.
- Though there is improvement in the hemoglobin level after stenting, the improvement is statistically non significant.
- There is definite andstatistically significant improvement in the values of total protein and and albumin after stenting
- The improvement in the values of Globulin in statistically non significant after 4 weeks , but the improvement is statistically significant in 8 weeks after stenting.
- The changes in the values of SGOT 4 weeks and 8 weeks after stenting are statistically non significant.
- The SGPT values increase statistically non significant in the first 4 weeks and significant in the 8 weeks after stenting.

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ஒப்புதல் படிவம்

மரு.பகவத் .பி.ஆர் ஆகிய நான் அரசு கோயம்பத்தூர் மருத்துவக்கல்லூரியின் பொது அறுவைச்சிகிச்சை த்துறையின் கீழ் உணவுக்குழாய் புற்றுநோயாளிகளின், உணவுக்குழாய் ஸ்டெண்டிங் சிகிச்சைக்குப்பின்னர் வாழ்க்கைத்தர உயர்வு குறித்த ஆய்வு என்ற தலைப்பில் ஆய்வு மேற்கொள்ள உள்ளேன்.

என் ஆய்வு வழிகாட்டி : மரு.பி.சுவாமிநாதன், எம்.எஸ் ,டி.ஒ, அவர்கள்.

ஆய்வின் நோக்கம் :

உணவுக்குழாய் புற்றுநோயாளிகளை வகைப்படுத்தல் , அவர்களுக்கான ஸ்டெண்டிங் சிகிச்சைக்கு முன் பின் வாழ்க்கைத்தரம் உயர்வு குறித்து ஆராய்தல்.

ஆய்வு மேற்கொள்ளும் இடம் : அரசு கோயம்பத்தூர் மருத்துவக்கல்லூரி மருத்துவமனை

ஆய்வினால் ஏற்படும் பக்கவிளைவுகள்: ஏதும் இல்லை

இந்த ஆய்வில் கிடைக்கும் தகவல்கள் வேறு எந்த ஆய்விற்கும் பயன்படுத்தப்பட மாட்டாது. அவை இரகசியமாக வைக்கப்படும்.

இந்த ஆய்வில் பங்கேற்க ஒப்புக்கொள்வதால் எந்த விதமான பலனும் உங்களுக்குக்கிடைக்காது.எந்த நேரத்திலும் ஆய்விலிருந்து விலகிக்கொள்ளும் உரிமை உங்களுக்கு உண்டு.ஆய்வில் இருந்த்ய் விலகுவதால் உங்களுக்கு அளிக்கப்படும் சிகிச்சையில் எந்த வித மாற்றமும் இருக்காது.

இந்த ஆராய்ச்சிக்காக உங்களிடம் சில கேள்விகள் கேட்கப்படும்.சில ரத்த மாதிரிகள் திசு மாதிரிகள் எடுக்கப்படும்.

மேலும் இந்த ஆய்வில் பங்கு கொள்வது உங்கள் சொந்த விருப்பம் .இதில் எந்த விதக்கட்டாயமும் இல்லை.

ஆய்வாளரின் கையொப்பம் :

நான்.

ஆய்வுக்குட்படுபவரின் ஒப்புதல் :

நான் இந்த ஆராய்ச்சியின் நோக்கம் மற்றும் அதன் பயன்பாட்டினைப்பற்றி தெளிவாகவும்,விளக்கமாகவும் தெரியப்படுத்தப்பட்டுள்ளேன் இந்த ஆராய்ச்சியில் பங்கு கொள்ளவும்,இந்த ஆராய்ச்சியின் மருத்துவரீதியான குறிப்புகளை வரும் காலத்திலும் பயன்படுத்திக்கொள்ளவும் முழுமனதுடன் சம்மதிக்கிறேன்.

ஆய்வுக்குட்படுபவரின் பெயர், முகவரி :

கையொப்பம் :

நாள் :

EORTC QLQ – OES18

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week:		Not at all	A little	Quite a bit	Very much
31.	Could you eat solid food?	1	2	3	4
32.	Could you eat liquidised or soft food?	1	2	3	4
33.	Could you drink liquids?	1	2	3	4
34.	Have you had trouble with swallowing your saliva?	1	2	3	4
35.	Have you choked when swallowing?	1	2	3	4
36.	Have you had trouble enjoying your meals?	1	2	3	4
37.	Have you felt full up too quickly?	1	2	3	4
38.	Have you had trouble with eating?	1	2	3	4
39.	Have you had trouble with eating in front of other people?	1	2	3	4
40.	Have you had a dry mouth?	1	2	3	4
41.	Have you had problems with your sense of taste?	1	2	3	4
42	Have you had trouble with coughing?	1	2	3	4
43.	Have you had trouble with talking?	1	2	3	4
44.	Have you had acid indigestion or heartburn?	1	2	3	4
45.	Have you had trouble with acid or bile coming into your mouth?	1	2	3	4
46.	Have you had pain when you eat?	1	2	3	4
47.	Have you had pain in your chest?	1	2	3	4
48.	Have you had pain in your stomach?	1	2	3	4

கடந்த வாரத்தில் தாங்கள் உணவு உட்கொள்ளும் பொழுது உணர்ந்ததைப்பற்றிய கேள்விகளுக்கு விடையளிக்கவும் :

	இல்லை	சிறிது	ஓரளவு	நன்றாக
1)தங்களால் கெட்டியான உணவுப்பொருட்களை உண்ண முடிகிறதா?	1	2	3	4
2) தங்களால் மிருதுவான சத்தி போன்ற உணவு உண்ண முடிகிறதா?	1	2	3	4
3)தங்களுக்கு நீர் மற்றும் பானங்கள் பருக முடிகிறதா?	1	2	3	4
4)தங்களுக்கு உமிழ்நீர் விழுங்குவதில் சிரமம் உள்ளதா?	1	2	3	4
5)உணவு விழுங்கும் பொழுது அடைப்பு ஏற்படுகிறதா?	1	2	3	4
6)உணவை அறுவெறுத்து உட்கொள்வதில் சிரமம் உள்ளதா?	1	2	3	4
7)உண்ட பின் வெகு விரைவாக வயிறு நிரம்பியது போல் உணர்கிறீர்களா?	1	2	3	4
8)உணவு உட்கொள்வதில் சிரமம் உள்ளதா?	1	2	3	4
9)மற்றவர் முன்பு உணவு உண்பதில் சிரமம் உள்ளதா?	1	2	3	4
10)வாய் உலர்வது போன்ற உணர்வு ஏற்படுகிறதா?	1	2	3	4
11) உணவுச் சுவை உணர்வதில் பிரச்சனை ஏற்படுகிறதா?	1	2	3	4
12)இருமும் பொழுது சிரமம் ஏற்படுகின்றதா?	1	2	3	4
13)பேசும் பொழுது சிரமமாக உள்ளதா?	1	2	3	4
14)அதிகமாக நெஞ்செரிச்சல் போன்றவை ஏற்படுகின்றனவா?	1	2	3	4
15)தலைப்புளிப்பு அல்லது மீத்தக்கசப்பை வாயில் உணர்கிறீர்களா?	1	2	3	4
16)உணவு உண்ணும் பொழுது வலி ஏற்படுகின்றதா?	1	2	3	4
17)தொக்கப்பகுதியில் வலி ஏற்படுகிறதா?	1	2	3	4
18)வயிற்றுப்பகுதியில் வலி ஏற்படுகின்றதா?	1	2	3	4

மொருத்தமான பதில்களின் கீழ் கொடுக்கப்பட்டுள்ள எண்ணில் வட்டமிட்டு குறிக்கவும்.

EORTC QLQ - OES18 - தமிழாக்கம்

Sl.No	Name	hosp number	Age	sex	height	pre weight	post weight1	post weight 2	tobacco smoking	chewing tobacco	Alcohol	urban/rural	comorbidity	pathology type
1	Chellappan	34969	52	M	168	55	54	55	yes	no	yes	urban	No	squamous
2	Sundarrajan	43735	67	M	170	54	55	56	yes	no	yes	urban	No	squamous
3	Balasubramaniar	44093	66	M	174	68	67	65	yes	no	yes	urban	No	squamous
4	Palanisamy	45859	69	M	178	70	70	72	yes	yes	yes	urban	HT /DM	squamous
5	Mohammed Han	55956	55	M	169	75	74	72	yes	yes	yes	urban	DM	squamous
6	Manikkam	55951	63	M	168	60	59	59	yes	yes	yes	urban	No	squamous
7	Firoza	28060	50	F	166	52	52	54	no	no	no	urban	No	adeno
8	Krishnamoorthy	28006	73	M	169	60	61	62	yes	no	yes	urban	No	adeno
9	Suseela	65296	62	F	152	52	52	53	no	yes	no	urban	No	adeno
10	Saroja	63659	55	F	155	50	50	53	no	yes	no	urban	DM	adeno
11	Joseph	27228	53	M	172	43	44	44	yes	no	yes	urban	No	squamous
12	Arukathal	26538	55	F	154	46	46	47	no	no	no	urban	No	adeno
13	Ganesan	50397	48	M	176	62	61	62	yes	no	no	urban	No	squamous
14	Panchalingam	48652	54	M	179	71	72	73	yes	no	yes	urban	No	squamous
15	Iroja	13100	45	F	160	51	50	51	no	yes	no	urban	No	adeno
16	Bakiyam	34213	49	F	158	46	48	48	no	yes	no	urban	No	squamous
17	Rajalakshmi	56643	56	F	163	53	55	55	no	yes	no	urban	No	adeno
18	Sundaram	52118	64	M	170	60	60	61	yes	no	yes	urban	DM	squamous
19	Subbulakshmi	51342	63	F	165	59	60	61	no	no	no	urban	No	adeno
20	Karuppasamy	56344	50	F	158	50	52	53	yes	no	yes	urban	No	adeno
21	Velumani	58862	73	M	178	73	73	74	no	no	no	rural	No	adeno

Sl.No	Name	location	stage	pre qol score dysphagia	post qol score 1 dysphagia	post qol score2 dysphagia score	post qol score3 dysphagia	pre qol gen health	post qol gen health1	post qol gen health 2	post qol gen health 3
1	Chellappan	Middle 3rd	3	6	12	16	16	32	20	18	12
2	Sundarrajan	Middle 3rd	3	8	16	16	16	34	22	18	15
3	Balasubramanian	lower 3rd	3	4	12	16	16	36	27	15	16
4	Palanisamy	Middle 3rd	3	6	12	16	16	32	26	18	14
5	Mohammed Hanifa	Middle 3rd	4	6	16	16	16	30	24	18	12
6	Manikkam	Middle 3rd	4	6	12	12	16	36	27	18	12
7	Firoza	lower 3rd	3	8	12	16	16	34	26	18	14
8	Krishnamoorthy	lower 3rd	3	4	12	16	16	32	22	15	15
9	Suseela	lower 3rd	3	4	12	16	16	30	27	14	14
10	Saroja	lower 3rd	3	6	12	16	16	30	27	12	15
11	Joseph	Middle 3rd	3	8	12	12	16	36	30	12	16
12	Arukathal	lower 3rd	3	8	12	12	16	36	32	14	14
13	Ganesan	Middle 3rd	3	6	12	16	12	34	27	16	14
14	Panchalingam	Middle 3rd	3	8	16	16	16	32	28	14	12
15	Iroja	lower 3rd	3	4	8	12	16	34	32	15	15
16	Bakiyam	Middle 3rd	3	6	12	16	16	30	30	12	12
17	Rajalakshmi	lower 3rd	4	6	16	16	16	32	32	13	12
18	Sundaram	Middle 3rd	3	8	8	12	16	30	26	15	9
19	Subbulakshmi	lower 3rd	4	6	16	16	16	32	22	14	9
20	Karuppasamy	lower 3rd	3	4	12	16	1	34	24	12	12
21	Velumani	Middle 3rd	3	6	12	16	12	36	22	15	12

Sl.No	Name	pre qol pain score	post qol pain 1	post qol pain 2	post qol pain 3	pre hb	post hb1	post hb 2	preTLC	preBlood sugar
1	Chellappan	9	12	6	4	10.8	11	12	9000	108
2	Sundarrajan	6	6	3	3	9.7	10.2	10.5	11020	97
3	Balasubramanian	9	9	4	4	10.2	10	10.8	8050	86
4	Palanisamy	6	9	3	4	11.4	11.4	11.6	7900	256
5	Mohammed Hanifa	6	12	6	4	12.4	12.6	13	6350	208
6	Manikkam	6	12	6	3	10.6	11	12.4	9090	79
7	Firoza	5	9	6	4	8.9		9	9870	64
8	Krishnamoorthy	9	9	4	3	12.9	12	12.4	12000	98
9	Suseela	6	12	6	4	10.2	10	9.8	7060	128
10	Saroja	6	9	6	5	9.7	10	10	6090	117
11	Joseph	9	12	6	5	12.2	10	11	4080	296
12	Arukathal	9	9	6	6	10.9	11	11.2	5780	96
13	Ganesan	6	9	6	6	12.9	13	12.8	7960	88
14	Panchalingam	9	9	4	4	11.6	11.8	12.4	8920	96
15	Iroja	9	12	4	4	10	10.2	10.8	9320	79
16	Bakiyam	6	12	4	3	9	9.2	10.8	7690	88
17	Rajalakshmi	6	12	6	4	7.2	7.6	8.4	4040	96
18	Sundaram	9	9	8	4	8.2	8.2	8	8620	98
19	Subbulakshmi	6	12	9	2	11.4	11.6	11.6	12040	204
20	Karuppasamy	6	9	6	4	10	10.4	11	9020	168
21	Velumani	6	6	4	4	11	11	10.4	4920	89

Sl.No	Name	post blood sugar1	Post blood sugar2	pre urea	post urea 1	post urea2	pre creatinine	post creatinine1	post creatinine 2	pre albumin	pre globulin
1	Chellappan	110	98	45	38	23	0.8	0.9	0.7	3.5	2.5
2	Sundarrajan	92	112	48	32	28	1.1	1.1	1	2.5	1.5
3	Balasubramanian	94	89	35	42	32	1.2	1	1.1	3.8	2.1
4	Palanisamy	200	168	38	38	26	0.7	0.7	0.9	4.2	3.1
5	Mohammed Hanifa	180	145	33	43	28	1.5	1.4	1.2	4.3	2.8
6	Manikkam	82	117	23	36	32	1.4	1	1.2	3.9	2.7
7	Firoza	88	121	43	38	36	1	1.2	1	3	2.4
8	Krishnamoorthy	96	110	42	46	30	0.8	0.8	0.7	3.9	2.1
9	Suseela	120	122	46	42	36	1.3	0.7	0.8	4.1	1.7
10	Saroja	104	98	40	36	28	0.8	0.8	0.6	2.7	2.8
11	Joseph	220	180	34	33	40	1.2	1.2	1.1	3.6	2.2
12	Arukathal	94	120	28	28	32	1.4	1.6	1.3	3.8	1.5
13	Ganesan	86	98	29	34	39	0.6	0.6	1	3.9	1.8
14	Panchalingam	78	109	36	36	34	0.8	0.9	1.1	4.8	2.1
15	Iroja	74	110	38	33	28	0.9	0.7	1.3	4.1	1.9
16	Bakiyam	96	89	33	25	24	1.2	1.2	1	3.3	2.6
17	Rajalakshmi	96	121	36	28	32	0.9	0.9	1.2	3.2	1.7
18	Sundaram	92	108	25	32	38	0.6	1.4	1	3.4	3
19	Subbulakshmi	164	154	55	50	40	0.7	1	0.9	4.2	2.8
20	Karuppasamy	148	140	60	58	48	1	0.8	0.7	3	2.7
21	Velumani	82	90	28	32	36	1.4	1.5	1.1	3.2	2

Sl.No	Name	pre total proteins	post albumin1	post globulin 1	post total proteins 1	post albumin2	post globulin 2	post total proteins 2	pre bilirubin	pre SGOT	pre SGPT	post bilirubin1	post bilirubin 2	post sgot1	post sgot 2	post sgpt1	post sgpt 2
1	Chellappan	6	3.9	2.6	6.5	3.9	2	5.9	1	32	27	1.1	9	32	40	28	35
2	Sundarrajan	4	3.5	2	5.5	3.8	1.8	5.6	1.2	35	32	1	8	36	38	24	45
3	Balasubramanian	5.9	4	2.6	6.6	3.6	2	5.6	1.1	32	28	1	1.2	34	45	30	40
4	Palanisamy	7.3	4.5	3	7.5	3.9	2.2	6.1	0.6	36	25	0.9	0.8	40	39	29	46
5	Mohammed Hanifa	7.1	3.9	2.6	6.5	4	2.4	6.4	0.9	42	22	0.7	0.9	39	45	49	45
6	Manikkam	6.6	4.2	2.5	6.7	4.2	2	6.2	0.7	37	28	1.1	1	32	35	76	35
7	Firoza	5.4	3.3	2	5.3	3.9	1.8	5.7	0.6	38	30	0.8	0.9	29	30	27	38
8	Krishnamoorthy	6	3.6	1.9	5.5	4.3	2	6.3	0.9	40	39	1.4	1.2	30	36	38	39
9	Suseela	5.8	3.2	2	5.2	4.4	1.8	6.2	1	36	32	0.7	0.9	35	38	32	43
10	Saroja	5.5	3.8	1.8	5.6	4.2	2.2	6.4	0.8	47	28	0.9	0.7	32	35	46	42
11	Joseph	5.8	3.8	2	5.8	4.5	3	7.5	0.6	32	32	0.8	0.8	38	50	38	54
12	Arukathal	5.3	4	2.9	6.9	2.6	4.2	6.8	0.9	30	44	1	0.9	28	46	34	55
13	Ganesan	5.7	3.9	1.8	5.7	3.9	2	5.9	0.8	33	42	1.1	1	24	42	29	56
14	Panchalingam	6.9	4.4	2	6.4	4.3	2.4	6.7	1.2	35	34	1.4	0.9	30	43	39	46
15	Iroja	6	4.2	2.7	6.9	4.6	2.9	7.5	0.6	49	37	0.9	0.8	36	38	46	40
16	Bakiyam	5.9	4	2.8	6.8	3.9	2.8	6.7	1.1	32	26	0.6	0.8	40	36	54	44
17	Rajalakshmi	4.9	3.9	3	6.9	4.4	2.4	6.8	0.9	50	38	0.8	1	22	35	30	39
18	Sundaram	6.4	4.2	2.6	6.8	3.8	3	6.8	0.6	30	40	1	1.1	39	45	24	50
19	Subbulakshmi	7	4	2.8	6.8	4.4	2.7	7.1	0.8	28	38	0.7	0.8	32	40	26	54
20	Karuppasamy	5.7	3.9	2	5.9	4.3	3	7.3	1	32	36	0.8	0.9	36	36	40	55
21	Velumani	5.2	3.6	1.9	5.5	4.5	2	6.5	0.8	36	42	1	1.2	34	38	36	40