

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

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### Abstract

**Background:** Placement of a Self-Expanding Metallic Stent (SEMS) has become the preferred treatment modality for the palliation of dysphagia due to carcinoma esophagus. 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. **Materials and Methods:** 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 (SEMS) were studied over the period of one year from July 2021 to June 2022 in a tertiary care centre. This study is a prospective study. The questionnaire consists of 18 questions in three categories to assess dysphagia, the general health and social activities related quality of life and the pain related quality of life after 1, 4 and 8 weeks. **Result:** 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 was also statistically significant. **Conclusion:** Self-Expanding Metallic Stent (SEMS) improves relief of dysphagia, significant improvement in personal, social health related quality of life, improvement in pain, hemoglobin level, total protein and albumin after esophageal stenting.

## INTRODUCTION

Esophageal carcinoma is one among the diseases with lowest five-year survival rate.<sup>[1]</sup> 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.<sup>[1,2]</sup> 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.<sup>[2,3]</sup> 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 anesthetic 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 parenteral nutrition) are usually avoided because of increased infection rates, higher costs and TPN cannot be used for long period of time.

The SEMS is 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 the 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.

## **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 July 2021 to June 2022 in a tertiary care center.

Study design: This study is a prospective study.

#### **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

$$n = 2 \times \{z\alpha + z\beta\}^2 \times \{SD\}^2 / \{M_{case} - M_{ctrl}\}^2$$

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<sup>4</sup>

$\{M_{case} - M_{ctrl}\} = 39$  effect size<sup>4</sup>

$M_{case} = 112, M_{ctrl} = 73$

Based on above calculation, the estimated sample size required for this study was around 21 cases<sup>4</sup>.

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**

##### **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.

##### **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, mean, Standard deviation and p value were calculated. A 'p' value less than 0.05 is taken to indicate the statistical significance.

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 QLQ c30 OES 18 questionnaire
2. Complete hemogram,
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 also underwent a detailed clinical examination. A questionnaire based enquiry of quality of life and psycho morbidity was administered to all the subjects before the esophageal stenting which is a part of standard treatment protocol.

##### **Post intervention assessment**

All subjects were evaluated for improvement of quality of life with the EORTC QLQ c30 OES 18 questionnaire, after the placement of covered SEMS at the end of 4 weeks and 8 weeks.

All subjects were evaluated with following standard laboratory tests at the end of 1, 4 and 8 weeks after the placement of SEMS.

1. Complete hemogram.
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 after collecting the details including medical history and clinical examination of the subject, the 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 OES 18 questionnaire.

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 18 questions. First 4(four) questions represent the dysphagia score.

The response options for 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 drink liquids? 1 2 3 4
4. Whether the patients able to swallow saliva? 1 2 3 4.

Response 1 point- Not at all, Response 2- A little, Response 3- Quite a bit and Response 4- Very much. Questions from 8 to 15 represent the general health and social activities related quality of life. Response 4 for each question indicates maximum impairment in quality of life and if the response is 1, it indicates no impairment.

8. Whether patients had trouble with eating?

1 2 3 4

9. Whether patients had trouble with eating in front of other people? 1 2 3 4

10. Whether patients had a dry mouth? 1 2 3 4

11. Whether patients had problems with your sense of taste? 1 2 3 4

12. Whether patients had trouble with coughing? 1 2 3 4

13. Whether patients had trouble with talking? 1 2 3 4

14. Whether patients had acid indigestion or heartburn? 1 2 3 4

15. Whether patients had trouble with acid or bile coming into their mouth? 1 2 3 4

The question items from 16 to 18 indicate the pain related quality of life. Response 4 denotes maximum pain perception response and response 1 denotes no pain perception.

16. Whether patients had pain when they eat? 1 2 3 4

17. Whether patients had pain in their chest? 1 2 3 4

18. Whether patients had pain in their stomach? 1 2 3 4

Thus the quality of life was measured in three categories.

The question items 5, 6 and 7 were omitted due to ambiguity in point calculation and not considered for calculation.

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

## RESULTS

**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 <sup>2</sup> )	20.63 ± 2.27
Tobacco smoking	12 (57.1%)
Tobacco chewing	8 (38.1%)
Alcohol intake	11 (52.4%)
Histopathology type	
	Adenocarcinoma 10 (47.6%)
	Squamous cell carcinoma 11 (52.4%)
Location of tumour	
	Mid third of esophagus 11 (52.4%)
	Lower third of esophagus 10 (47.6%)
Stage of cancer	
	Stage III 17 (81.0%)
	Stage IV 4 (19.0%)
Dysphagia Grade	
	Grade3 16(76.2%)
	Grade4 5(23.8%)

Total 21 subjects 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.

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%).

In histopathology type, the number of adenocarcinoma was 10(47.6%) and the number of squamous cell carcinoma was 11(52.4%).

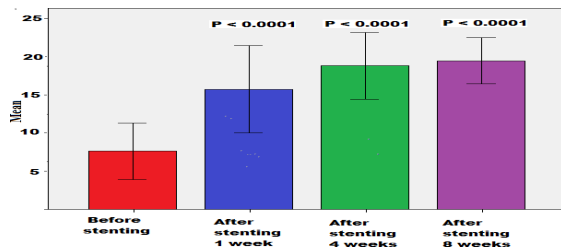
In 11(52.4%) patients the tumor was located in the middle third and 10(47.6%) patients had tumor in the lower third of esophagus.

The number of patients with Stage 3 disease and severe dysphagia were 17(81%) and stage 4 disease was 4(19%).

Four patients were with Diabetes mellitus (19%) and 12 patients were with Hypertension (57%).

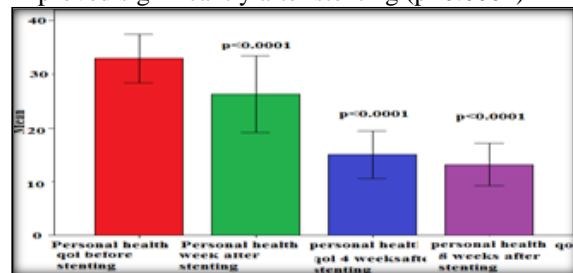
Twenty patients (95.2%) were from urban area and only one patient (4.76%) was from rural area.

There was stent migration observed in one patient (4.76%) 4 days after stenting for which reinsertion was done.



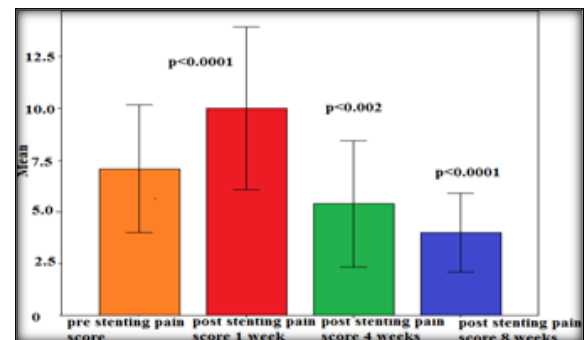
**Figure 1: Comparison of dysphagia score before and after stenting for esophageal cancer. The bars represent the mean score of dysphagia and the error bar indicates standard deviation.**

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



**Figure 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.**

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

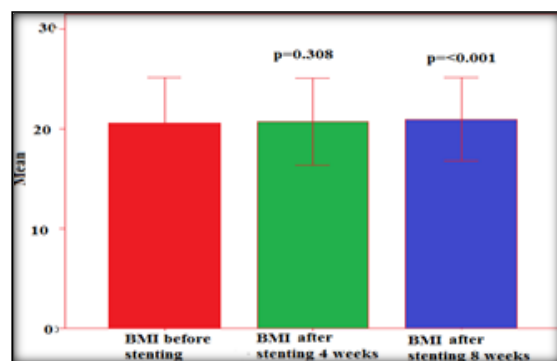


**Figure 3: Comparison of pain score before and after stenting for esophageal cancer. The bars represent the mean score of Pain and the error bar indicates standard deviation.**

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

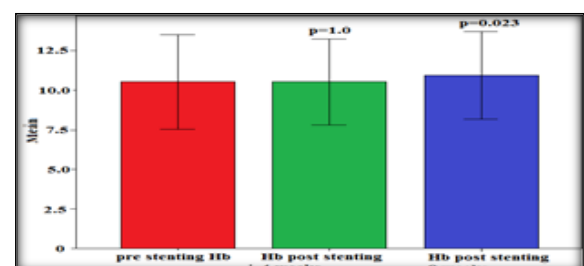
**Table 2: The symptom burden and global health of subjects before and after stenting**

Variables	Before stenting	One week after stenting	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



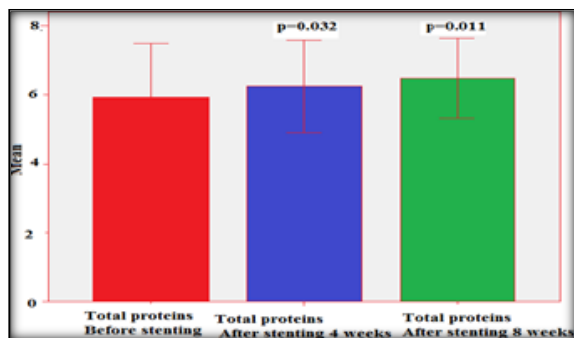
**Figure 4: Comparison of BMI score before and after stenting for esophageal cancer. The bars represent the mean score of BMI and the error bar indicates standard deviation**

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



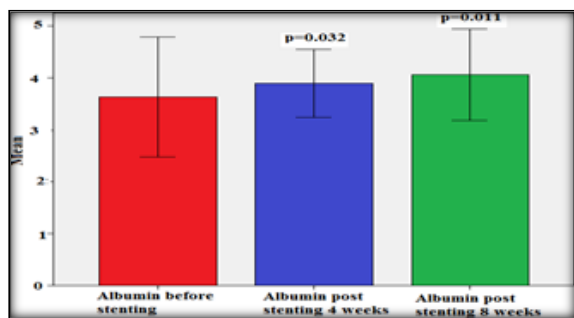
**Figure 5: Comparison of Hemoglobin score before and after stenting for esophageal cancer. The bars represent the mean score of Hemoglobin and the error bar indicates standard deviation**

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



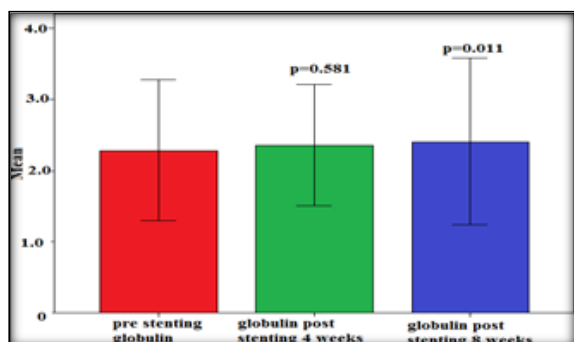
**Figure 6:** Comparison of Total protein score before and after stenting for esophageal cancer. The bars represent the mean score of Total proteins and the error bar indicates standard deviation

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



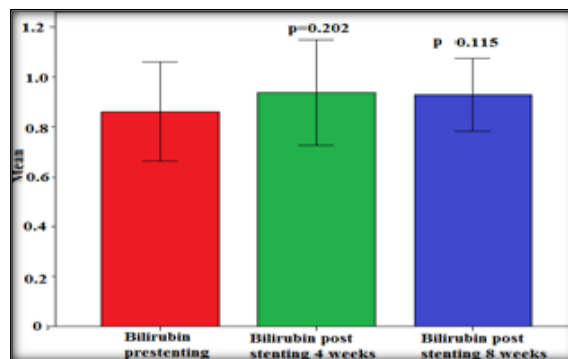
**Figure 7:** Comparison of Albumin score before and after stenting for esophageal cancer. The bars represent the mean score of Albumin and the error bar indicates standard deviation

The improvement of Albumin level is statistically significant 4 weeks ( $p=0.032$ ) and 8 weeks ( $p=0.011$ ) after stenting.



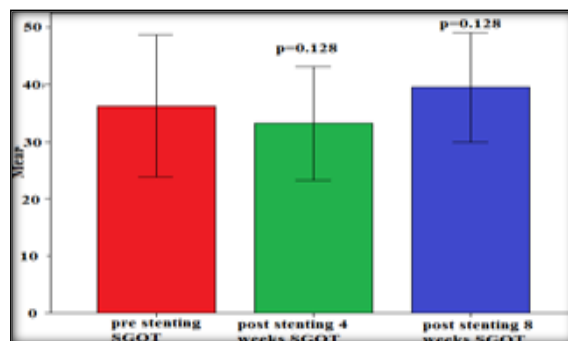
**Figure 8:** Comparison of Globulin score before and after stenting for esophageal cancer. The bars represent the mean score of Globulin and the error bar indicates standard deviation

The improvement of globulin level is non-significant statistically after 4 weeks ( $p=0.581$ ) but the improvement is significant 8 weeks ( $p=0.011$ ) after stenting.



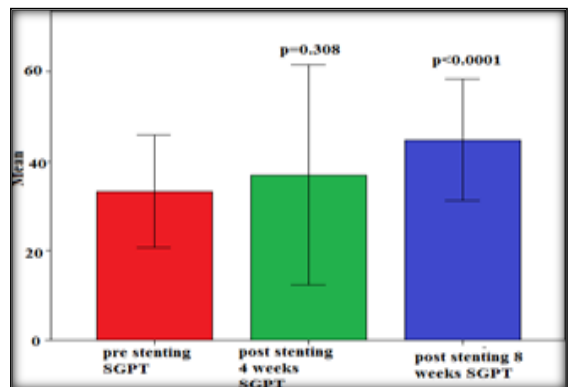
**Figure 9:** Comparison of Total Bilirubin score before and after stenting for esophageal cancer. The bars represent the mean score of Total Bilirubin and the error bar indicates standard deviation.

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.



**Figure 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.

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



**Figure 11:** Comparison of SGPT score before and after stenting for esophageal cancer. The bars represent the mean score of SGPT and the error bar indicates standard deviation.



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

**Table 3: Comparison of anthropometric and biochemical variables in subjects before and after stenting**

variables	Before stenting	Four week after stenting	Eight weeks after stenting
BMI (kg /height m <sup>2</sup> )	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± 0.21	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

## 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.<sup>[1]</sup>

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 AIIMS, New Delhi, Madhusudhan et al.<sup>[5]</sup> 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 c30 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 by Nanda Kishore Maroju et al.<sup>[6]</sup> in the Department of Surgery, JIPMER, Pondicherry- 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.<sup>[4]</sup> Turkey, 170 patients were 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.<sup>[7]</sup> 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 c30 OES 23 questionnaire. Statistically Significant improvement was noted in the SEMS group. In our study also, the dysphagia relief is significant after 7 days, 4 weeks and 8 weeks respectively.

Another study conducted by Martin et al.<sup>[8]</sup> 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 SEMS was safe, not only the dysphagia relief is significant, but also economically beneficial and cost effective compared with the failed or multiple dilatation procedures.

Cochrane Database, Interventions for dysphagia in oesophageal cancer, Dai Y, Li C et al.<sup>[9]</sup> concluded that SEMS are safer and more effective than plastic stents.

## CONCLUSION

Esophageal Stenting by Self Expanding Metallic Stent (SEMS) improves relief of dysphagia, significant improvement in personal, social health related quality of life, improvement in pain and hemoglobin level.

We were also able to appreciate improvement in biochemical markers like total protein and albumin after esophageal stenting.

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