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폐암에 의한 연하곤란에서의 식도 스텐트와 경피적 위루술의 비교 연구

김지혜, 민양원, 이혁, 민병훈, 이준행, 이풍렬, 김재준
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Comparative Study of Esophageal Self-expandable Metallic Stent Insertion and Gastrostomy Feeding for Dysphagia Caused by Lung Cancer

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Background/Aims: Dysphagia is encountered in a large proportion of patients with lung cancer and is associated with malnutrition and a poor quality of life. This study compared the clinical outcomes of self-expandable metallic stent (SEMS) insertion and percutaneous gastrostomy (PG) feeding for patients with lung cancer and dysphagia.
Methods: A total of 261 patients with lung cancer, who underwent either SEMS insertion (stent group) or PG (gastrostomy group) as an initial treatment procedure for dysphagia between July 1997 and July 2015 at the Samsung Medical Center, were reviewed retrospectively, and 84 patients with esophageal obstruction were identified. The clinical outcomes, including the overall survival, additional intervention, complications, and post-procedural nutritional status in the two groups, were compared.
Results: Among the 84 patients finally analyzed, 68 patients received SEMS insertion and 16 had PG. The stent group had less cervical obstruction and more mid-esophageal obstruction than the gastrostomy group. The Kaplan-Meier curves revealed similar overall survival in the two groups. Multivariate analysis showed that the two modalities had similar survival rates (PG compared with SEMS insertion, hazard ratio 0.682, p=0.219). Fifteen patients (22.1%) in the stent group received additional intervention, whereas there was no case in the gastrostomy group (p=0.063). The decrease in the serum albumin level after the procedure was lower in the gastrostomy group than in the stent group (-0.20±0.54 g/dL vs. -0.65±0.57 g/dL, p=0.013)
Conclusions: SEMS insertion and PG feeding for relieving dysphagia by lung cancer had a comparable survival outcome. On the other hand, PG was associated with a better nutritional status. **(Korean J Gastroenterol 2018;71:124-131)**

Key Words: Self expandable metallic stents; Gastrostomy; Esophageal stenosis; Lung cancer; Dysphagia

INTRODUCTION

Lung cancer is the leading cause of cancer death in men and is showing an increasing trend in women. In addition, it was the highest ranked cancer by the absolute years of life lost in 2015.[1] Dysphagia has been reported in 1-5% of lung cancer patients at presentation.[2] The percentage experiencing dysphagia increases to 6-7% during the full clinical course.[2-4] The dysphagia associated with lung cancer could be accounted for by the following mechanisms: esophageal involvement or extrinsic compression by lung tumor or bulky mediastinal lymph nodes; impaired swallowing function re-

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lated to a brain metastasis or oropharyngeal involvement; and esophageal stenosis or esophagitis due to radiotherapy.[5-7] Dysphagia may play a role as a high symptom burden affecting the nutritional intake and development of malnutrition, with the potential to affect the patient-related and treatment outcomes.[8]

The treatment options for the palliation of dysphagia caused by malignant esophageal obstructions include esophageal stents, percutaneous gastrostomy, surgery, dilation, radiation therapy, and laser ablation.[9,10] Although the choice depends on the mechanism of dysphagia, fully or partially covered self-expandable metallic stent (SEMS) placement and percutaneous gastrostomy (PG) are used widely for palliation. SEMS placement may improve the dysphagia rapidly and can make patients take food through their mouths into their stomachs. On the other hand, complications, including severe retrosternal pain, fistula, or recurrent dysphagia requiring additional procedures, tend to occur over a longer period of stent use.[11,12] In contrast, PG which cannot restore the swallowing function itself appears to have a lower rate of severe complications than stents.[13] Nevertheless, no study has compared the two modalities with respect to the survival rate or complications in a lung cancer setting. Therefore, this study compared the clinical outcomes between SEMS insertion and PG feeding in patients with lung cancer and malignant dysphagia.

SUBJECTS AND METHODS

1. Study population

A total of 261 patients with lung cancer underwent either SEMS insertion or PG between 1997 and 2015 at the Samsung Medical Center in Seoul, Korea. The patients were diagnosed with lung cancer by a histopathological examination. The procedures were performed endoscopically or radiologically. Although this study was designed retrospectively and there were no absolute indications for choosing SEMS placement or PG, patients who wanted to maintain the oral intake preferred SEMS placement. The exclusion criteria to select the patients eligible for both procedures were as follows: 1) bronchoesophageal fistula without an esophageal obstruction (n=33); 2) stricture due to radiotherapy (n=23); 3) underwent the procedure because of an impaired swallowing function itself, such as central nervous systemic, oropharyngeal or post-operative transient problems (n=115); 4) underwent the procedure previously at another hospital (n=2); and 5) malignant dysphagia due to other primary cancers (n=4). Finally, 68 patients who received SEMS insertion (stent group) and 16 patients who received PG (gastrostomy group) for feeding were analyzed (Fig. 1).

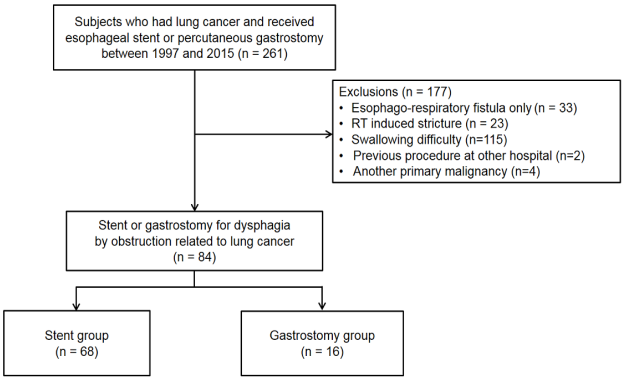

Fig. 1. Flow chart of patient selection. RT, radiotherapy.

2. Data collection

The following data were collected as the baseline characteristics: age, sex, tumor stage according to 7th American Joint Committee on Cancer (AJCC) staging system,[14] tumor histology, location of stenosis, stenotic length by the tumor (determined by endoscopy, esophagography, or computed tomography), history of cancer specific treatment, such as chemotherapy or radiotherapy after the procedure, body weight, body mass index, and serum albumin level. Data with regard to the occurrence of procedure-related complications, the presence of aspiration pneumonia, treatment with chemotherapy or radiotherapy, and changes in body weight and serum albumin level after the procedure were also acquired. The changes in weight and albumin level were determined by the values measured 1 to 2 months after the procedure. Pneumonia was defined when a patient received antibiotic therapy according to newly developed pulmonary infiltration on the chest radiograph or computed tomography scan and symptoms, such as fever, tachypnea, purulent sputum, or dyspnea. The all-cause mortality and the presence of additional interventions following the procedure (SEMS insertion or PG) were also investigated. Additional intervention included stent insertion, stent repositioning, gastrostomy, and removal of stent or gastrostomy due to an insufficient effect or complications.

3. Outcomes

The primary outcome was the survival, which was estimated by the all-cause mortality. The secondary outcomes were as follows: the need for additional intervention, number of additional interventions, presence of complications, and change in body weight or serum albumin level after the procedure. The procedure-related complications were confined to significant cases, including pneumonia, fistula, and presence of dyspnea, which required additional action; asymptomatic pneumoperitoneum was excluded.

4. Statistical analysis

All statistical analyses were conducted using the SPSS 23 software package (IBM Corporation, Armonk, NC, USA). The data are reported as the mean±standard deviation, median (range), or number (%) of patients. Survival analyses were performed using the Kaplan-Meier method and the differences in the survival curves were assessed using a log-rank test. A t-test, Mann-Whitney test, and Fisher's exact test were used to compare the data regarding the baseline characteristics and secondary outcomes between the two groups. Cox proportional hazards models were used to estimate the hazard ratios for each type of procedure (SEMS or PG) after adjusting for the other baseline characteristics. For all analyses, two-sided tests of significance were used and a p-value less than 0.05 was considered significant.

Table 1. Comparison of Baseline Characteristics in Lung Cancer Patients Who Received either Esophageal Stent or Percutaneous Gastrostomy for Malignant Dysphagia

Variables	Stent group (n=68)	Gastrostomy group (n=16)	p-value
Age (years)	62.4±11.5	58.5±6.3	0.069
Sex			0.214
Male	47 (69.1)	14 (87.5)	
Female	21 (30.9)	2 (12.5)	
BMI (kg/m^2)	20.0±2.68	20.2±3.05	0.725
Weight (kg)	51.0 (33.7-78.9)	54.4 (38.2-70.6)	0.197
Albumin (g/dL)	3.63±0.52	3.43±0.62	0.198
Histology			0.552
Adenocarcinoma	27 (39.7)	6 (37.5)	
Squamous cell carcinoma	27 (39.7)	8 (50.0)	
Small cell lung cancer	6 (8.8)	2 (12.5)	
Others	8 (11.8)	0 (0)	
Stage by AJCC 7th			0.611
NSCLC stage III	15 (22.1)	5 (31.3)	
NSCLC stage IV	47 (69.1)	9 (56.3)	
SCLC[a]	6 (8.8)[a]	2 (12.5)	
Location of stenosis			0.021
Cervical	1 (1.5)	2 (15.5)	
Upper thoracic	6 (8.8)	2 (12.5)	
Mid thoracic	49 (72.1)	6 (37.5)	
Lower thoracic	12 (17.6)	6 (37.5)	
Stenotic length			0.530
Near total obstruction	5 (7.4)	1 (6.3)	
≤3 cm	24 (35.3)	5 (31.3)	
>3 cm and ≤6 cm	26 (38.2)	9 (56.3)	
>6 cm	13 (19.1)	1 (6.3)	
CTx or RTx after procedure			
No	33 (48.5)	5 (31.3)	0.270
Yes	35 (51.5)	11 (68.8)	
CTx only	16	6	
RTx only	9	3	
CTx and RTx	10	2	

Values are presented as the mean±standard deviation, median (range) or n (%).
BMI, body mass index; AJCC, American Joint Committee on Cancer; NSCLC, non-small cell lung cancer; SCLC, small cell lung cancer; CTx, chemotherapy; RTx, radiotherapy.
[a]Among the SCLC patients, only one patient of stent group was limited stage and the others were extended stage.

5. Ethics statement

The study protocol was reviewed and approved by the Institutional Review Board of the Samsung Medical Center (No. 2017-08-066-001). The board waived the requirement for informed consent.

RESULTS

1. Baseline characteristics

Table 1 compares the baseline characteristics of the two groups. The mean age of the patients in the stent and gastrostomy groups was 62.4±11.5 and 58.5±6.3 years, respectively (p=0.069). No significant differences in age, sex, body mass index, serum albumin level, tumor histology, stage of lung cancer, stenotic length, and whether to receive cancer-specific chemotherapy or radiotherapy after the procedure were observed. The stent group had less cervical obstruction (1.5% vs. 15.5%) and more mid-esophageal obstruction (72.1% vs. 37.5%) than the gastrostomy group (p=0.021).

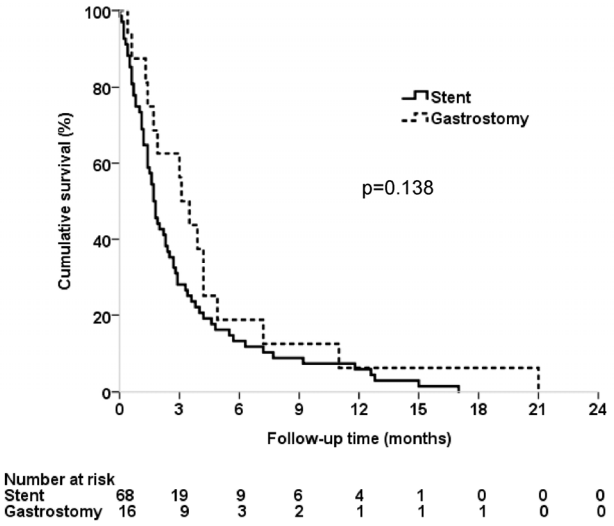

Fig. 2. Kaplan-Meier curves for the overall survival in lung cancer patients who received either esophageal stent or percutaneous gastrostomy for malignant dysphagia.

2. Overall survival

During a median follow-up of 1.8 months (interquartile range 2.7 months; maximum 21.0 months), the Kaplan-Meier curves revealed similar overall survival in the stent and gastrostomy groups (Fig. 2). Subgroup analysis according to the 7th AJCC staging in non-small cell lung cancer (NSCLC) patients showed that the stent group and gastrostomy group had similar survival (stage III, p=0.073 and stage IV, p=0.805, Fig.3). Multivariate analysis revealed a higher baseline albumin level and receiving chemotherapy or radiotherapy after the procedure (yes vs. no) to be positively related to a better survival (Table 2). On the other hand, the two treatment modalities had no significant difference in the survival rate.

3. Secondary outcomes

Table 3 compares the secondary outcomes in the two

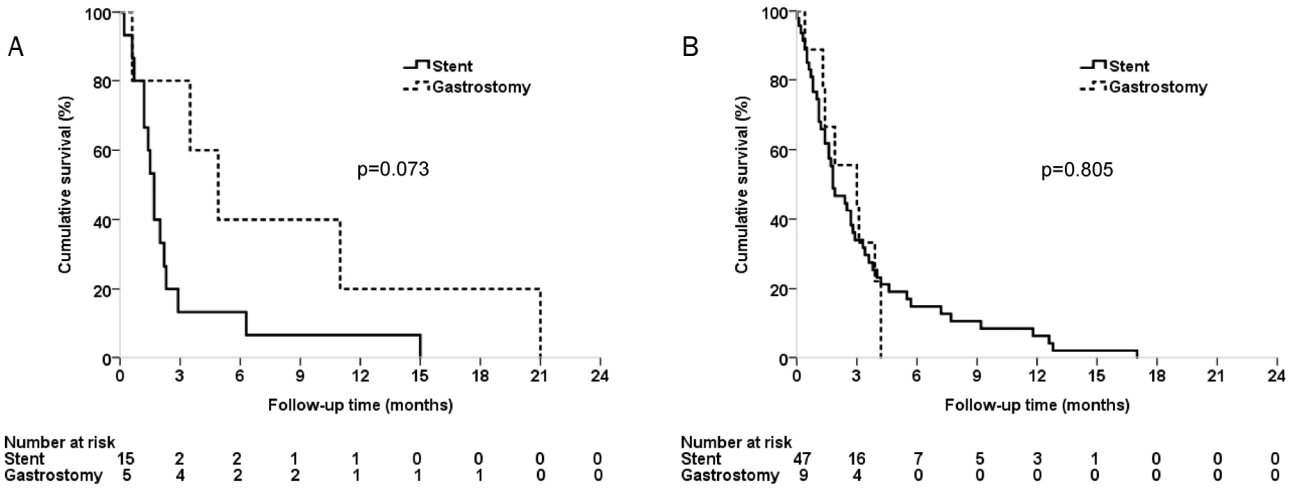

Fig. 3. Subgroup analysis of the overall survival according to the 7th AJCC staging in NSCLC patients. (A) Kaplan-Meier curves for the overall survival in NSCLC stage III patients who received either esophageal stent or percutaneous gastrostomy for malignant dysphagia. (B) Kaplan-Meier curves for the overall survival in NSCLC stage IV patients who received either esophageal stent or percutaneous gastrostomy for malignant dysphagia. AJCC, American Joint Committee on Cancer; NSCLC, non-small cell lung cancer.

Table 2. Prognostic Factors Associated with the Overall Survival in Patients with Dysphagia Induced by a Lung Cancer Obstruction

Variables	Univariate analysis		Multivariate analysis	
	HR (95% CI)	p-value	HR (95% CI)	p-value
Age (years)	1.021 (0.998-1.044)	0.075	1.008 (0.985-1.031)	0.487
Sex (male)	1.245 (0.766-2.024)	0.376		
BMI	0.976 (0.889-1.073)	0.618		
Albumin	0.600 (0.410-0.877)	0.008	0.594 (0.393-0.898)	0.014
Histology				
NSCLC	1			
SCLC	1.351 (0.649-2.816)	0.421		
Stage				
NSCLC III	1			
NSCLC IV	1.172 (0.692-1.984)	0.556		
SCLC LD	1			
SCLC ED	0.563 (0.058-5.467)	0.621		
Location of stenosis				
Cervical	1			
Upper thoracic	1.279 (0.336-4.864)	0.718		
Mid thoracic	1.804 (0.562-5.795)	0.322		
Lower thoracic	1.465 (0.426-5.036)	0.544		
Stenotic length				
≤3 cm	1			
>3 cm and ≤6 cm	1.047 (0.63-1.729)	0.858		
>6 cm	1.659 (0.868-3.167)	0.125		
Near total obstruction	0.806 (0.350-1.857)	0.613		
CTx or RTx after procedure				
Yes	1		1	
No	3.769 (2.332-6.092)	<0.001	3.352 (2.045-5.492)	<0.001
Intervention modality				
Stent	1		1	
Gastrostomy	0.659 (0.375-1.156)	0.146	0.682 (0.371-1.255)	0.219

HR, hazard ratio; CI, confidence interval; BMI, body mass index; NSCLC, non-small cell lung cancer; SCLC, small cell lung cancer; LD, limited-stage disease; ED, extensive-stage disease; CTx, chemotherapy; RTx, radiotherapy.

Table 3. Comparison of the Secondary Outcomes in Lung Cancer Patients Who Received either Esophageal Stent or Percutaneous Gastrostomy for Malignant Dysphagia

Variables	Stent group (n=68)	Gastrostomy group (n=16)	p-value
Additional intervention			
Need for additional intervention	15 (22.1)	0 (0)	0.063
Number of additional interventions, mean	0.25	0	0.061
Complications			
Number of total complications	1 (0-3)	0 (0-1)	0.067
Pneumonia	30 (44.1)	5 (31.3)	0.409
Fistula	9 (13.2)	0 (0)	0.196
Dyspnea	9 (13.2)	0 (0)	0.196
Nutrition			
Change in weight after the procedure (kg)	-1.00 (-8.1 to +8.0)	-0.35 (-5.7 to +1.1)	0.658
Change in serum albumin level after the procedure (g/dL)	-0.65±0.57	-0.20±0.54	0.013

Values are presented as the mean±standard deviation, median (range) or n (%).

groups. A total of 15 out of 68 (22.1%) of the stent group underwent additional intervention while no one out of the 16 patients in the gastrostomy group did, but there were no significant differences in the need for additional intervention or the number of additional interventions between the two groups (p=0.063 and p=0.061). Although the gastrostomy group showed no fistula or dyspnea after the procedure, the post-procedure complications were not significantly differ-

ent between the two groups in terms of pneumonia, fistula, and dyspnea. In addition to the above complications, two patients in the gastrostomy group were treated with antibiotics for several days due to post-procedure fever. The gastrostomy group showed a smaller decrease in the serum albumin levels after the procedure than the stent group (-0.20±0.54 g/dL vs. -0.65±0.57 g/dL, p=0.013). The post-procedure change in body weight was similar in the two groups.

DISCUSSION

Lung cancer is one of the most common malignancies worldwide and a substantial number of patients with lung cancer experience difficulty in swallowing. Dysphagia is one of the nutrition-impact symptoms that can lead to malnutrition and influence treatment completion, survival, quality of life, and physical function in lung cancer.[8] SEMS insertion and PG feeding are the most common procedural options for the palliation of malignant dysphagia. A few studies have compared the two procedures in some clinical settings, such as tracheoesophageal fistula or esophageal cancer.[15,16] To the best of the authors' knowledge, however, the present study is the first to compare the two procedures in patients with obstructive dysphagia related to lung cancer. The data showed that SEMS insertion and PG feeding performed for patients with lung cancer and dysphagia had a comparable survival outcome, even though the gastrostomy group showed a smaller decrease in the albumin level than the stent group and no requirement for additional intervention.

The basis of treatment for advanced lung cancer is chemotherapy and radiation therapy.[17,18] The nutritional status can affect lung cancer survival because it is one of the factors determining whether to perform cancer-specific treatment as well as on its own. Multivariate analysis revealed the baseline serum albumin level and postoperative chemotherapy or radiotherapy to be prognostic factors related to the overall survival rate. In addition to dysphagia due to narrowing of the esophagus, symptoms or treatment toxicity, such as anorexia, nausea, vomiting, and esophagitis, can compromise the oral intake.[19] Therefore, similar to the result of a study on SEMS insertion and esophageal cancer reported by Mao-de-Ferro et al., patients with lung cancer could continue to experience nutritional deterioration even after dysphagia is improved by SEMS insertion.[20] PG feeding can stabilize or improve the nutritional status of patients with dysphagia, head and neck cancer, and esophageal cancer with limited complications.[13,21-23] In the present study, the gastrostomy group showed a smaller decrease in the albumin level one to two months after the procedure compared to the stent group, even though the difference in the body weight changes after the procedure between the two groups did not reach significance. An interval of 1-2 months might be inadequate for the body weight to be indicative of the effect of nutritional intervention in cachexic patients with a limited life expectancy.

The better nutritional status of the gastrostomy group after procedure was not associated with an improvement in survival. In contrast, according to a recent study at the authors' institution comparing PG feeding and SEMS insertion in patients with esophageal cancer and dysphagia, PG was associated with a higher survival rate and better nutritional status than SEMS insertion.[16] The different results may be due to the difference in follow-up period that was affected directly by the survival rate of cancer itself. In the esophageal cancer study group, the stage of cancer ranged from II to IV, whereas in the lung cancer study group, all of the NSCLC patients were stage III or IV and all the small cell lung cancer patients except for one were in the extended stage. The esophageal cancer study group showed a median follow-up of 4.9 months (interquartile range 7.2 months; maximum 145.7 months), whereas that of the lung cancer study group was 1.8 months (interquartile range 2.7 months; maximum 21.0 months). When the Kaplan-Meier curves for the NSCLC patients were compared according to the stage, the difference between the gastrostomy group and stent group appeared more prominent in the stage 3 NSCLC group, even though it was not statistically significant.

In this study, the two procedure groups had a significantly different distribution of the location of stenosis. Although the two treatment modalities had the same indication making it possible to feed patients with an esophageal obstruction, the stent group had less cervical and distal esophageal obstruction than the gastrostomy group. This difference can be explained as follows. SEMS placement at the cervical esophagus is technically difficult due to neck pain and SEMS at the distal esophagus can cause post-procedure gastro-esophageal reflux. On the other hand, univariate analysis showed that the location of the stenosis was not a significant prognostic factor. The esophageal obstruction in patients with

lung cancer was caused mainly by the mediastinal lymph node (except for 3 patients out of the 84 study population who had a bulky primary tumor) and almost all of the patients were at a N stage of 2 and 3. As the vertical position of the metastatic lymph node, which caused the esophageal obstruction, is not the criteria of the N stage and cannot be the prognostic factor, it is believed that the difference in the location of the stenosis would not have a significant impact on this study.

Several studies have suggested that SEMS insertion has more frequent and serious side effects than PG,[11,12,24] but the present study revealed no significant differences in terms of additional intervention. As only patients with dysphagia with a malignant obstruction were included, many patients with lung cancer who underwent PG for other causes were excluded and the small number of the gastrostomy group would make it difficult to reach statistical significance. Indeed, in this study, no one in the gastrostomy group required additional intervention, whereas 22.1% of the stent group received additional intervention, including immediate removal or replacement of the device due to intolerable side effects, such as severe pain, dyspnea, or fistula.

This study had some limitations. First, the study had a retrospective design. When choosing which procedure to perform, a range of factors had already been considered. People who wanted to eat would have a stronger will to live and a better performance status. Moreover, SEMS insertion would not be selected for upper esophageal narrowing or the condition that airway stenosis is anticipated, which led to selection bias that may have favored the stent groups. Second, nutritional status was assessed using only the body weight and serum albumin level. Third, the quality of life was not surveyed and compared in the two groups, which is an important criterion in palliative care. A thorough review of the records showed no complaints in the gastrostomy group, whereas persistent poor oral intake, substernal pain, or dyspnea were often observed in the stent group. Fourth, the primary outcome was similar in the two groups.

Nevertheless, this study has important meaning. To the best of the authors' knowledge, this is the first study to compare the SEMS insertion and PG feeding in patients with lung cancer and obstructive dysphagia, which can be helpful when selecting the optimal procedure in actual practice.

In conclusion, PG feeding had no survival benefit compared to SEMS insertion, despite being associated with a better nutritional status than SEMS insertion.

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