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DISEASES OF THE ESOPHAGUS

Original article

Comparative study of different treatments for malignant tracheoesophageal/bronchoesophageal fistulae

Y. Hu, Y.-F. Zhao, L.-Q. Chen, Z.-J. Zhu, L.-X. Liu, Y. Wang, Y.-L. Kou

Department of Thoracic and Cardiovascular Surgery, West China Hospital, Sichuan University, Chengdu, Sichuan, China

SUMMARY. **The aim of this study is to compare the survival time and quality of life (QOL) of patients who have received different treatment for tracheoesophageal/bronchoesophageal fistula. Between January 2003 and December 2007, 35 patients with malignant tracheoesophageal/bronchoesophageal fistula were recorded as the control group, gastrostomy group, and stenting group, respectively, according to the treatments they chose. Two weeks after the treatment, European Organization for Research and Treatment of Cancer Quality of Life Core 30 Questionnaire (QLQ-C30), Quality of Life Questionnaire-esophageal module (QLQ-OES18), and a respiratory symptom-related QOL index are employed to assess QOL of these patients. There is no significant difference in survival time and constituent ratio of death reason among groups. Except for eight patients who died within 2 weeks after the treatment, all other 27 patients returned back the questionnaires. As compared to the control group, patients in the gastrostomy group gained a low score in emotional function and financial situation, while patients in the stenting group had lower scores in financial problems and seven respiratory and eating-related symptoms. In contrast with the gastrostomy group, patients in stenting group had higher scores in emotional and social functions, and lower scores in six respiratory and eating-related symptoms. With patients' QOL considered, the self-expandable coated stenting should be the first choice of therapy for malignant tracheoesophageal/bronchoesophageal fistula, whereas gastrostomy should be kept from use.**

KEY WORDS: **cancer, palliative care, quality of life, supportive care.**

INTRODUCTION

As an advanced complication of esophageal cancer, tracheoesophageal/bronchoesophageal fistulae are not uncommon.[1] The frequency was about 5–10% of such patients.[2,3] The abnormal communications between airway and esophagus lead to continuous contamination of the tracheobronchial tree and repeated respiratory infections. If not treated on time, patients will soon die of respiratory failure and malnutrition. The natural course is only several weeks.[4–6] Most patients died within 1 month.[7]

As bypass procedures have been phasing out nowadays, self-expandable coated stenting[8–10] and gastrostomy are becoming the two most commonly used methods for this distressing condition in our country. Previous studies only focused on the improvement of patients' survival time after the treatment, rarely taking their quality of life (QOL) into consideration. The aim of this study is to compare the survival time and QOL of patients who have accepted various therapies of this entity.

PATIENTS AND METHODS

Enrolled in this study were 35 consecutive patients who were diagnosed with tracheoesophageal/bronchoesophageal fistula secondary to esophageal squamous cell carcinoma in West China Hospital of Sichuan University from 2003 to 2007. The fistula was evidenced by bronchial endoscopy (3/3), esophageal endoscopy (19/28), and barium studies (32/35).

According to the treatment that the patients received, patients were nonrandomly divided into three groups. First, the stenting group: stents were successfully placed in 17 patients. All stents used in

Address correspondence to: Prof Yong-Fan Zhao, MD, Department of Thoracic and Cardiovascular Surgery, West China Hospital, Sichuan University, 37 Guoxuexiang, Chengdu, Sichuan 610041, China. Email: doctorzhaoyongfan@hotmail.com

our study were MTN-S-20-coated (Micro-Tech, Nanjing, China) self-expandable nitinol stents with a diameter of 20 mm and length of 80–120 mm. No sedation was given throughout the procedure. After a guidewire was placed through an Olympus GIF-XQ260 endoscope (Olympus, Tokyo, Japan), the stent was loaded on its introducer and slipped down to the right place with a pusher tube over the guidewire. Once released, the stent self-expanded to fix itself in the esophagus and seal the fistula. Flow diet was given from the second day after stent insertion. Antibiotics were also given. Second, the gastrostomy group: nine patients underwent gastrostomy for nutrition support (four patients refused stent for economic reasons, three patients had the fistulae too close to the upper esophageal sphincter [UES], a contraindication to stent insertion, and two had a failed stent implantation). The failure of stent placement was due to the complete obstruction of the distal esophagus. We could not send the guidewire through the stenosis; thus, the stent could not be inserted. Patients in this group underwent laparotomic gastrostomy and had a gastrostomic tube placed. Nutrition support through this tube began when enterokinesia was recovered. They received fasting and antibiotics. Third, the control group: nine patients refused either the stenting or gastrostomy procedure for economic reasons. They only received conservative therapy including fasting, antibiotics, and paraenteral nutrition support. The clinical characteristics of patients in each group were summarized in Table 1.

Health-related quality of life (HRQL) was assessed by three series of questionnaires. The commonly used series, the European Organization for Research and Treatment of Cancer Quality of Life Core 30 Questionnaire (EORTC QLQ-C30), is a 30-item cancer-specific questionnaire designed for clinical trials.[11] It is composed of five functional scales, three symptom scales, one global scale, and six single items. It is widely used to assess general HRQL of patients with cancer, such as esophageal cancer.[12]

As a supplement of EORTC QLQ-C30, EORTC Quality of Life Questionnaire-esophageal module (QLQ-OES18) is a site-specific module designed for patients of esophageal cancer.[13] It contains 18 items, which are divided into four symptom scales and six single items.

Items of both QLQ-C30 and QLQ-OES18 are written as questions. All of the scales and single-item measures range in score from 0 to 100, and a high score implies a high level of symptom or a high level of functioning or global QOL. The combination of QLQ-C30 and QLQ-OES18 is a common way to assess HRQL of patients suffering from esophageal cancer,[14] and it has been used to assess HRQL of Chinese patients.[15] Different from common patients of esophageal cancer, patients with tracheoesophageal/bronchoesophageal fistula often have conspicuous respiratory symptoms. These symptoms, although apparently affect HRQL of patients, can hardly be fully reflected in the above two questionnaires. So, an 8-item questionnaire has been developed by pulmonologist and thoracic surgeons from our institution referring to the literature.[16] This respiratory symptom-related quality of life index (RSRQLI) is composed of eight questions concerning with bucking when swallowing, coughing,

Table 1 Clinical characteristics of patients in each group

	Control group ($n = 9$)	Gastrostomy group ($n = 9$)	Stenting group ($n = 17$)	P
Gender (male/female)	7/2	7/2	15/2	0.714
Age (year)	59.56 ± 4.77	57.33 ± 8.60	56.83 ± 7.72	0.448
Therapies for ESCC before the development of fistula				0.997
None	4	4	9	
Surgery alone	1	1	1	
Radiotherapy alone	0	1	1	
R + C	2	2	4	
Surgery + R + C	2	1	2	
Type of fistula (TEF/BEF)	6/3	5/4	10/7	0.882
Manifestations at the beginning of treatments				
Dysphagia	9	8	16	1.000
Intractable cough	8	7	15	0.749
Copious mucus	7	7	14	1.000
Fever	6	5	11	0.867
Respiratory failure	1	2	2	0.749
Hemoptysis	2	1	1	0.483
Hematemesis	0	1	0	0.514
Weight loss (%)	7.22 ± 3.42	8.56 ± 5.03	7.76 ± 3.35	0.656
Interval between onset of fistula and start of treatment (day)†	28.56 ± 31.97	32.00 ± 16.53	33.35 ± 22.90	0.560
Further chemotherapy	0	2	5	0.200

Data are expressed as the number of patients or mean ± standard deviation.
†For the control group, interval means the time delay between the onset of fistula and admission to hospital. BEF, bronchoesophageal fistula; C, chemotherapy; ESCC, esophageal squamous cell carcinoma; R, radiotherapy; TEF, tracheoesophageal fistula.

expectoration, hemoptysis, fever, short breath, treatment for respiratory symptoms, and the impact of these symptoms on patients' life. All questions are graded from 1 to 4, with grade 4 implying the most dysfunctional situation. The higher the total score, the more severe the respiratory symptoms were.

Taking into account the limited survival time of these patients and the impact of surgery on QOL, HRQL assessments were performed about 2 weeks after gastrostomy or stent insertion. For patients in the control group, HRQL was assessed for about 2 weeks after the admission. HRQL assessment was performed in a hospital and arranged by telephone or post. One telephone reminder was made if required. After the postal questionnaires were returned, they were scrutinized for missing items. If there were some missing items, patients were telephoned for responses to eliminate the missing data.

Follow-up was performed once a month. Survival time and cause of death were recorded. Statistics analysis was performed by using SPSS 11.5 package for Windows (SPSS Inc., Chicago, IL, USA). The cumulative survival was described by Kaplan–Meier method and analyzed by log–rank test. The categorical data were analyzed by means of χ^2 test or Fisher's exact test. Parametric data were analyzed by using Kruskal–Wallis test. A *P*-value less than 0.05 was considered significant.

RESULTS

As shown in Table 1, the baseline characteristics of different groups were similar. In the control group, respiratory symptoms were relieved to varying degree in six patients after the supportive treatments. While in the gastrostomy group, seven patients had their respiratory symptoms relieved to varying degree after the gastrostomy procedure. Two patients died perioperatively, one with massive bleeding and the other with malnutrition and cachexia. All the 17 patients in the stenting group had a successful stent implantation. Fistula failed to be sealed in only one patient, which was manifested by a remaining cough when swallowing. After an inefficient endoscopic adjustment, the patient eventually received another airway stenting 3 days after the esophageal stent insertion. Then, the respiratory symptoms were relieved. There were four perioperative deaths. Causes of death were massive bleeding in one patient, pneumonia and respiratory failure in one patient, and unclear (suspicious cardiac insufficiency) in the remaining two patients.

The stent-related problems are summarized as follows.

1 Pain. There were four patients who complained of chest pain or odynophagia, but all the symptoms disappeared within 2 weeks without any intervention.
2 Stent migration. One stent migrated caudally 4 days after the insertion. The clinical manifestation was the relapse of cough when swallowing. The migration was confirmed by X-ray film, and was adjusted to the original place by endoscopic reposition.
3 Restenosis. Restenosis occurred in three patients because of the progression of tumor at a mean of 57 days (45, 60, 66 days, respectively). One of them received another stent-inserted surgery and had this problem resolved. The other two patients, until death, refused any further adjustment except supportive therapy.
4 Massive bleeding. Massive bleeding occurred in five patients in the stent group at a mean of 34 days (3, 20, 23, 59, and 66 days, respectively). Because most patients stayed home when bleeding occurred and the interval between the onset of bleeding and death was short, the causes of bleeding were not very clear. Three of these patients presented with hematemesis and melena, and the other two patients manifested with hemoptysis. All these five patients died within 2 days after the onset of bleeding.

The causes of death in each group are shown in Table 2.

Survival analysis

The median of survival time for each group is demonstrated in Table 2, and the survival curve is shown in Figure 1. Although the median survival time of the stenting group (93 days) seems much longer than that of both the control group (66 days) and the gastrostomy group (62 days), no statistical difference between groups is found by log–rank test ($P = 0.476$).

Table 2 The survival time and cause of death

	Control ($n = 9$)	Gastrostomy ($n = 9$)	Stenting ($n = 17$)	*P*
Median survival time/interquartile range (day)	66/(20–119)	62/(41–111)	93/(44–165)	0.476
Cause of death				
Massive bleeding	3	2	5	0.722
Pneumonia, respiratory failure	2	2	4	
Malnutrition, cachexia	4	5	6	
Unclear	0	0	2	

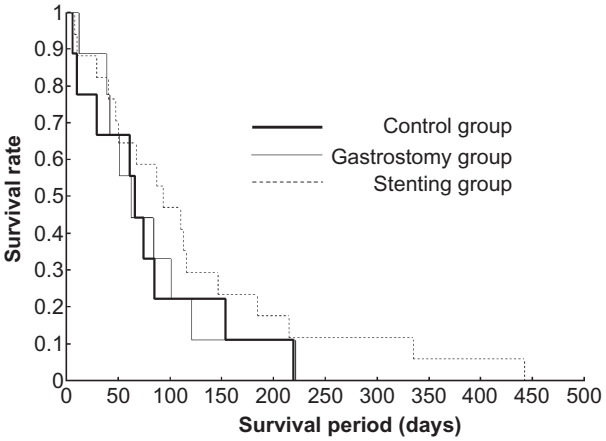

Fig. 1 Survival after the treatment of tracheoesophageal/bronchoesophageal fistulae.

Assessment of the QOL

Eight patients died within 2 weeks after the treatment, two in the control group, two in the gastrostomy group, and four in the stenting group. HRQL assessment was not performed on these eight patients. All the remaining 27 patients returned completed questionnaires, seven each in both the control group and the gastrostomy group, and 13 in the stenting group. Scores of HRQL are presented in Table 3.

As compared with the control group, patients in the gastrostomy group only scored significantly lower in emotional function and financial problems, while patients in the stenting group scored much lower in finance-related items and items concerning the following seven symptoms: dyspnea, dysphagia, eating problems, dry mouth, cough, saliva problems, and respiratory problems (shown by RSRQLI).

In comparison with the gastrostomy group, patients in the stenting group have higher scores in emotional and social function, and lower scores in the following six symptoms: dyspnea, dysphagia, dry mouth, saliva problems, and respiratory problems (shown by RSRQLI).

DISCUSSION

At present, the common treatments for patients with malignant tracheoesophageal/bronchoesophageal fistula include coated self-expandable stenting, gastrostomy, and gastric bypass procedure. At the

Table 3 Scores of HRQL after therapy

	Control ($N = 7$)		Gastrostomy ($n = 9$)		Stenting ($N = 17$)		
	Median	IQR	Median	IQR	Median	IQR	*P*-value
EORTC QLQ-C30							
Physical	60	40–73	67	47–73	67	53–77	0.482
Role	33	17–50	33	33–50	33	33–50	0.614
Emotional	42	25–58	25	17–33	50	42–58	0.006†§
Cognitive	50	33–67	50	33–50	50	50–67	0.364
Social	33	17–33	33	17–33	50	33–50	0.044§
Overall QOL	25	17–25	25	17–25	25	25–38	0.054
Fatigue	44	33–78	44	33–67	44	33–50	0.842
Nausea and vomiting	0	0–17	17	0–17	0	0–17	0.622
Pain	33	0–50	33	0–50	33	0–59	0.838
Dyspnea	66	33–66	33	33–33	0	0–33	0.010‡§
Problems sleeping	67	33–67	67	33–67	33	17–67	0.154
Anorexia	67	33–100	67	33–100	33	33–67	0.188
Constipation	0	0–33	0	0–67	0	0–17	0.541
Diarrhea	0	0–0	0	0–33	0	0–33	0.461
Financial problems	67	67–100	33	0–67	33	0–50	0.027†‡
EORTC QLQ-OES18							
Dysphagia	57	44–78	56	56–67	22	22–33	0.000‡§
Eating	75	58–75	67	67–83	33	25–33	0.000‡§
Pain	22	0–22	11	11–22	11	0–22	0.639
Reflux	17	0–33	17	0–17	17	0–25	0.753
Dry mouth	33	33–67	33	33–33	0	0–33	0.003‡§
Taste	33	0–33	33	0–66	33	0–33	0.482
Cough	66	33–66	33	0–33	0	0–33	0.003‡
Speech	0	0–33	0	0–0	0	0–0	0.156
Trouble swallowing saliva	33	33–33	33	0–33	0	0–0	0.000‡§
Choking	0	0–0	0	0–0	0	0–0	0.565
RSRQLI							
RSRQLI	16	12–18	15	12–17	11	9–12	0.000‡§

†Significant difference found between control group and gastrostomy group. ‡Significant difference found between control group and stenting group. §Significant difference found between gastrostomy group and stenting group. EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30; EORTC QLQ-OES18, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-esophageal module; HRQL, health-related quality of life; IQR, interquartile range QOL, quality of life; RSRQLI, respiratory symptom-related quality of life index.

advanced stage of esophageal cancer, which is usually complicated with refractory pneumonia, these patients usually present themselves with poor physical conditions. Surgical palliation of tracheoesophageal/bronchoesophageal fistula would expose these patients to high procedure-related risk. For their high perioperative mortality of about 30%,[17] these bypass procedures have little place today. On the contrary, a coated self-expandable stent is easy to position with the assistance of a flexible endoscopy. With a procedure-related complication incidence of 0–17% and a mortality of 0–2%,[18–20] coated self-expandable stenting has become the most frequently employed method for treating malignant tracheoesophageal/bronchoesophageal fistulae. The only drawback is its high cost. Not every patient would like to choose this. This economic problem was more conspicuous in developing countries such as China. As a traditional way of fistula management, gastrostomy is known to be effective on palliating respiratory symptoms. So, for those patients who could not afford stenting or failed in the insertion of a stent, gastrostomy was an alternative. There were also a few patients, as those in our control group, who received only supportive therapy for economic reasons.

So far, today, most researchers evaluated these treatments only with the survival time or incidence of complications, ignoring the patients' QOL. Actually, as shown in the study, no matter which treatment the patients take, their survival time and the constituent ratio of their death reason do not change significantly. Therefore, it is the HRQL that should be considered as a determinant factor in choosing treatment for these patients.

Through this study, we also find that the coated self-expandable stenting is the most effective way to improve HRQL of patients with malignant tracheoesophageal/bronchoesophageal fistula. This can be reflected from the following three aspects:

First, stenting can significantly improve eating difficulties.

The endoesophageal coated self-expandable stents can effectively palliate the malignant obstruction, and can expand within their circumstance, tightly fitting with esophagus. Seldom moving or causing ischemic necrosis, these stents are very efficient in sealing off fistula.[18–20] As a result, almost all patients can swallow liquid and soft diet right after stent insertion surgery. Generally speaking, Stenting can resolve three problems which cannot be solved by other treatments: (i) Patients could not enjoy the fun of eating; (ii) feeding became a very inconvenient procedure. Patients had to rely on the people around; and (iii) inconvenient feeding could result in augmenting nutritional support. This can be proven by the lower score in the stenting group in the symptom of dry mouth.

Second, stenting can effectively relieve the respiratory symptoms.

The endoesophageal coated self-expandable stents can satisfactorily occlude the fistula in more than 90% of patients,[21,22] protecting the tracheobronchial tree from continuous contamination of saliva and food particles. Thus, the lung infections can be controlled soon in most patients, while the other two treatments do nothing to address problems associated with fistulization, and aspiration continues to be a significant concern. So the respiratory symptoms of patients in the stenting group were much more unremarkable than that in the other two groups.

Third, stenting can positively affect the psychological function of patients.

We found that patients in the stenting group scored much higher in emotional and social function than patients in the gastrostomy group, and in social function than patients in the control group. These differences are perhaps due to three reasons: (i) the difference in respiratory symptoms; (ii) the difference in feeling when eating; and (iii) the discomfort that the gastrostomy tube brings to patients.

Thus, the coated self-expandable stenting should be the best treatment for patients with malignant fistulae. Although there would be some problems when placing the stents, for example, the fistula might not be sealed completely, or complete obstruction could make the insertion difficult, or the fistula was close to the UES, there are ways to solve them now. Colt and Albes *et al.*[23–27] have proposed airway stent or combined use of endoesophageal stent and airway stent as a remedy to incomplete blockage for fistula. One patient in our study had his problem resolved in this way. Rehders[28] reported a patient with complete obstruction and esophagorespiratory fistula. After a laparotomy, retrograde dilatation via a duodenal incision endoscopic was achieved. Then, it was possible to place an esophageal stent via an antegrade approach. The additional laparotomy is worthwhile because the patient could have the stent inserted, and the QOL could be improved significantly. Verschuur and colleagues[29] reported their study on the efficacy and safety of stent placement in patients with a malignant obstruction close to the UES. They found that stent placement close to the UES is safe and effective for the palliation of dysphagia and sealing of fistulae. Thus, more patients that used to be considered unsuitable for stent treatment could get stent therapy.

Usually, gastrostomy is considered as the ultimate choice to treat malignant fistula especially when stenting finds its failure, because gastrostomy can partially palliate the respiratory symptoms and establish a relatively inexpensive means of nutritional support. But the truth that we discovered in the study is that, apart from bringing additional mental suffering and feeding inconvenience, gastrostomy is not superior in improving survival time or abating

respiratory symptoms to some simple supportive therapies, such as fasting, antibiotics, and intravenous nutritional support. Consequently, gastrostomy should be kept from use.

In conclusion, although endoesophageal coated self-expandable stenting could not significantly prolong the survival time of patients, it could remarkably improve the HRQL. Therefore, it should be considered as the first choice of treatment for malignant tracheoesophageal/bronchoesophageal fistula. Even if the palliation of respiratory symptoms is unsatisfactory, airway stenting or double stenting should be used as plan B instead of gastrostomy.

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