

Retrospective Study

Predictors of the patency of self-expandable metallic stents in malignant gastroduodenal obstruction

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Abstract

AIM: To investigate the predictive factors of self-expandable metallic stent patency after stent placement in patients with inoperable malignant gastroduodenal obstruction.

METHODS: A total of 116 patients underwent stent placements for inoperable malignant gastroduodenal obstruction at a tertiary academic center. Clinical success was defined as acceptable decompression of the obstructive lesion within the malignant gastroduodenal neoplasm. We evaluated patient comorbidities and clinical statuses using the World Health Organization's scoring system and categorized patient responses to chemotherapy using the Response Evaluation Criteria in Solid Tumors criteria. We analyzed the relationships between possible predictive factors and stent patency.

RESULTS: Self-expandable metallic stent placement was technically successful in all patients (100%), and the clinical success rate was 84.2%. In a multivariate Cox proportional hazards model, carcinoembryonic antigen (CEA) levels were correlated with a reduction in stent patency [$P = 0.006$; adjusted hazard ratio (aHR)

= 2.92, 95%CI: 1.36-6.25]. Palliative chemotherapy was statistically associated with an increase in stent patency ($P = 0.009$; aHR = 0.27, 95%CI: 0.10-0.72).

CONCLUSION: CEA levels can easily be measured at the time of stent placement and may help clinicians to predict stent patency and determine the appropriate stent procedure.

Key words: Malignant gastroduodenal obstruction; Stent; Patency; Predictive factor; Carcinoembryonic antigen

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Core tip: Self-expandable metallic stent placement is an effective palliative treatment in patients who have inoperable malignant gastroduodenal obstruction. However, clinical parameters associated with stent patency have been controversial. This retrospective study investigated the potential predictive factors of stent patency. We found that carcinoembryonic antigen level is an easily determined parameter that is associated with stent patency in malignant gastroduodenal obstruction.

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INTRODUCTION

Up to 20% of patients with progressive pancreatic or peripancreatic malignancies may experience symptoms caused by gastric outlet obstruction, including nausea, vomiting, dehydration, and poor nutrition, which cause considerable morbidity^[1,2]. Surgical gastrojejunostomy has been considered a classic treatment option for malignant gastroduodenal obstruction. While surgical gastrojejunostomy offers good functional outcomes and symptom improvements have been noted in 72% of patients^[3], it can have high rates of mortality (2%-36%) and morbidity (13%-55%)^[4]. Poor outcomes following gastrojejunostomy have been reported in past studies^[5,6]. Additionally, this surgical procedure is not appropriate for patients whose physical status prevents them from tolerating surgery.

Recently, self-expandable metallic stent (SEMS) insertion has emerged as an effective and feasible technique for the palliation of inoperable malignant gastroduodenal obstruction. SEMS insertions can facilitate the rapid resumption of oral intake and shorter hospital stays compared to the hospital stays required

for gastrojejunostomies^[7-9]. However, complications that include stent migration and tumor overgrowth frequently occur after SEMS placement^[4,10], and, although rare, severe complications such as bleeding and perforations can occur. In addition, providing a variety of treatments for gastrointestinal cancer could prolong patient survival for those who have malignant gastroduodenal obstruction. Therefore, estimating SEMS patency after it has been inserted is important for determining its effectiveness as a palliative therapy for malignant gastroduodenal obstruction. However, few published studies are available that describe the predictive factors of stent patency in patients who have undergone SEMS placements for the palliative treatment of inoperable malignant gastroduodenal obstruction^[11-13]. Some studies have reported that chemotherapy is a prognostic factor significantly associated with increased stent patency^[11,14]. Additionally, malignant obstructive lesions^[15,16] and the type of SEMS inserted^[17] have been shown to be possible prognostic factors. Controversies remain about these predictive factors, and demand is increasing for simple and effective predictive factors that are associated with stent patency in inoperable malignant gastroduodenal obstruction.

Carcinoembryonic antigen (CEA) is a frequently used tumor marker, and its levels are usually elevated in the serum of patients who have colorectal carcinomas, gastric carcinomas, and pancreatic carcinomas^[18]. However, its value in evaluating stent patency has not been fully elucidated.

This study aimed to assess the efficacy of SEMS and to determine possible predictive factors associated with stent patency in the palliative therapy of malignant gastroduodenal obstruction.

MATERIALS AND METHODS

Patients

We retrospectively collected data relating to stent placement procedures performed between January 2006 and April 2013. A total of 116 patients underwent stent placements for malignant gastroduodenal obstruction at the Korea University Medical Center, and, of these, 56 patients were enrolled to participate in this study. The inclusion criteria for this study were patients who had inoperable malignant gastroduodenal obstruction and patients who had symptoms caused by gastroduodenal obstruction. The exclusion criteria were patients who had benign strictures, patients who had surgery performed after stent placement, and patients for whom a CEA value was not recorded when the stent was inserted. This study was reviewed and approved ethically by the Korea University Anam Hospital Institutional review board (IRB No. ED13047).

Stent characteristics

We used Hanarostent SEMS (M. I. Tech, Seoul, South

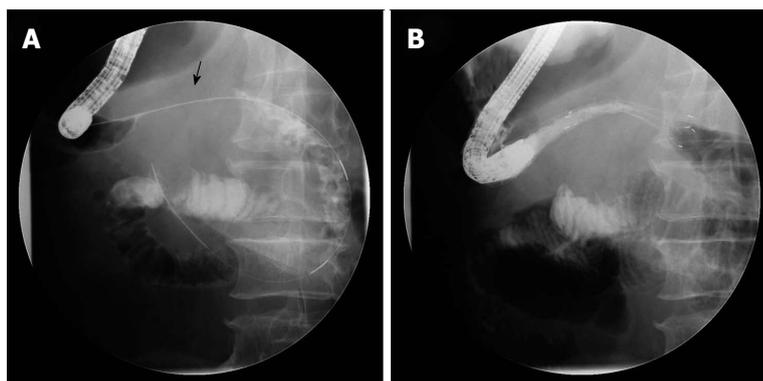


Figure 1 Gastric outlet obstruction. A: The injection of the contrast medium shows the stricture (arrow); B: A 9 cm stent was successfully placed, and the passage of contrast medium was visible.

Korea). The stents' diameters were 18-20 mm and they were 60-160 mm long. Of the 56 stent placements, covered stents were used in 27 patients and uncovered stents were used in the remaining patients. The physician who performed the stent placements decided which stent type to use based on the clinical situation. The size of the stent was chosen based on the approximate dimensions of the stricture, and its length was determined by adding 20 mm to the stricture length on both sides.

Stent placement

We used a GIF-H260 endoscope (Olympus Optical Co., Ltd, Tokyo, Japan) in this study. An experienced endoscopist successfully inserted all of the stents using a combined endoscopic and fluoroscopic method (Figure 1). The details of the stent deployment procedure used have been described in a previous study^[19]. The stent placement procedure was performed while the patients were under standard conscious sedation induced by propofol and/or midazolam and in either the left decubitus position or the prone position. Patients were advised to consume water or a liquid diet on the day of the procedure and a soft diet on the day following the procedure.

Clinical outcomes and definitions

The duration of stent patency was defined as the time from stent insertion to the time that stent dysfunction occurred due to tumor ingrowth or stent migration. If no complications that were associated with the stent arose, the duration of stent patency was considered to be identical to the patient's duration of life or the last day the patient visited the hospital. The technical success of the stent was defined as its successful placement at the site of the obstruction. Clinical success was defined as acceptable decompression of the obstructive lesion within the malignant gastroduodenal neoplasm, and clinical success was confirmed when there were indications that the obstructive symptoms had been relieved; namely, the resumption of oral food intake and the resolution of obstructive signs on

abdominal radiographs^[20]. The gastric outlet obstruction scoring system (GOOSS) was also used to assess oral dietary intake levels before and after the procedure^[21]. We evaluated the patients' comorbidities and clinical statuses using the World Health Organization's scoring system^[22]. We categorized the patients' responses to chemotherapy using the Response Evaluation Criteria in Solid Tumors criteria^[23]. A responder to chemotherapy was defined as a patient who had a complete response, a partial response or stable disease after chemotherapy, while a non-responder was defined as a patient who had progressive disease after chemotherapy.

We analyzed the relationships between possible predictive factors and stent patency.

Follow-up

The relief of obstructive symptoms was assessed during the follow up period using endoscopy, using abdominal radiography, and from patient interviews. The patients were followed until stent failure or death. The reasons underlying stent failure were categorized as restenosis, migration, stent fracture, or any other reason that interrupted stent patency. Symptoms and signs were monitored during the follow-up period and used to indicate stent failure. When stent failure was suspected, abdominal radiographic and endoscopic evaluations were performed to assess stent patency. The data were obtained from clinical records, endoscopic reports, and radiologic reports.

Statistical analysis

The independent samples *t*-test and Fisher's exact test were used to compare the variables. We compared the CEA levels between the study cohorts based on stent dysfunction using the Mann-Whitney *U* test. The optimal cut-off value of CEA for predicting stent patency was determined using a receiver operating characteristic (ROC) curve. The area under the ROC curve and the significance level were analyzed. A Cox proportional hazards regression model was used to analyze the significance of the relationship between the possible predictive factors and stent patency in

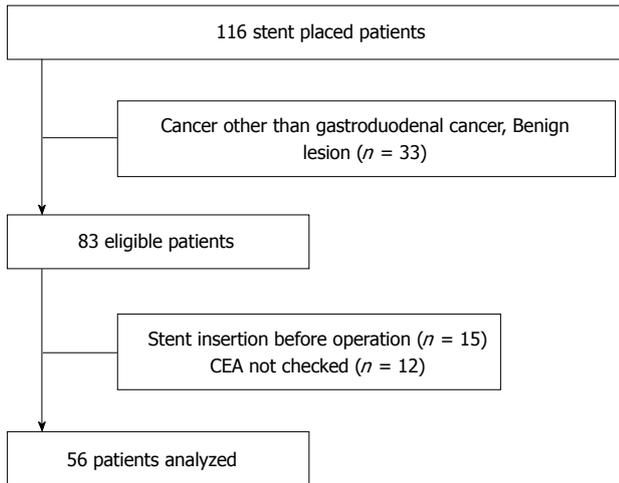


Figure 2 Study flow chart. CEA: Carcinoembryonic antigen.

malignant gastroduodenal obstruction. Those patients whose follow-up assessments were discontinued were censored. The *P* values were derived from two-tailed tests, and a *P* value < 0.05 was considered significant. The statistical analyses were performed using PASW Statistics for Windows, Version 18.0 (SPSS Inc., Chicago, IL, United States). The statistical methods of this study were reviewed by Kyung Sook Yang from Department of Biostatistics, Korea University College of Medicine, Seoul, South Korea.

RESULTS

A total of 116 patients underwent stent placements for gastroduodenal obstruction at the Korea University Medical Center between January 2006 and April 2013, and, of these, 83 patients underwent SEMS insertions for malignant gastroduodenal obstruction. Fifteen patients were excluded from the study because they underwent surgery after stent insertion, and 12 patients (14.5%) were excluded from the study because their CEA level was not measured when the stents were inserted. Consequently, 56 patients were included in the final analyses (Figure 2). None of the patients underwent radiotherapy.

The characteristics of the patients who were included in the final analyses are summarized in Table 1. The patients were admitted to the hospital for a mean duration of 15.7 d. The most common stage of malignancy was Stage IV. Twelve patients started chemotherapy within 2 wk prior to stent insertion, while the remaining patients started chemotherapy within 4 wk after stent insertion. Chemotherapy was not administered to patients who had comorbid conditions or did not wish to receive chemotherapy.

Clinical outcomes and complications

No acute complications, including perforations or aspiration pneumonia, were noted in patients after stent insertion, and there were no stent insertion-

Table 1 Characteristics of the patient population, *n* = 56

Characteristic	<i>n</i> (%)
Mean age, yr (range)	69 (52-91)
Sex (men:women)	36:20 (64.3:35.7)
Chemotherapy	37 (66.1)
Etiology	
Gastric cancer	35 (62.5)
Pancreatic cancer	21 (37.5)
Cancer status	
Locally advanced	5 (8.9)
Metastasis	51 (91.1)
Stent	
Covered	27 (48.2)
Uncovered	29 (51.8)
WHO score	
1	49 (12.5)
2	7 (87.5)
GOOSS score	
0	19 (33.9)
1	36 (64.2)
2	1 (1.8)
3	0 (0)

GOOSS: Gastric outlet obstruction scoring system; WHO: World Health Organization.

related deaths. SEMS placement was technically successful in all of the patients (100%), and the clinical success rate was 84.2%. We evaluated clinical improvements in the gastric outlet obstruction using the GOOSS score. The GOOSS score was 0.67 before stent insertion and 2.42 after stent insertion. Each of the patients for whom the procedure was clinically successful showed improvements in their post-stent oral consumption.

Stent migration occurred in two patients (3.5%), and stent ingrowth occurred in 13 patients (23.2%). The sources of the malignancies in the patients who experienced stent migration were the stomach (*n* = 1) and the pancreas (*n* = 1). Both patients underwent stent placement using covered stents and received chemotherapy after stent insertion. When a stent migrated, it was immediately replaced by another stent.

Factors associated with stent patency

Univariate analysis showed that there was no significant difference in relation to sex, age, the procedural time, the types of obstructive lesion, the stent type, the presence of peritoneal carcinomatosis, and the stage of cancer between the groups that were delineated based on stent dysfunction (Table 2). The mean CEA level was higher in the group that experienced stent failure, but the difference was not statistically significant. ROC analysis, using the duration of stent patency as a classification variable, determined that the cut-off value for CEA was 6 ng/mL (*P* = 0.019; 95%CI: 0.53-0.78) (Figure 3). The CEA levels were compared in relation to the types of malignancy (Figure 4).

We used Cox proportional hazards models to assess the factors that were anticipated to be associated

Table 2 Comparison of patient characteristics according to stent failure *n* (%)

	Stent failure		P value
	Yes (<i>n</i> = 40)	No (<i>n</i> = 16)	
Age (yr)	67 ± 13.2	73.9 ± 12.1	0.72
Sex			0.43
Men	27 (67.5)	9 (56.2)	
Women	13 (32.5)	7 (43.8)	
Procedure time (min)	36.4 ± 19.9	31.5 ± 18.6	0.39
Chemotherapy	29 (72.5)	8 (50)	0.10
Response	13 (32.5)	1 (6.3)	0.09
CEA (ng/mL)	31.1 ± 111.5	5.1 ± 5.9	0.39
Type of stent			0.31
Covered	21 (52.5)	6 (37.5)	
Uncovered	19 (47.5)	10 (62.5)	
Carcinoma peritonei	14 (35.0)	6 (37.5)	0.86
Cancer stage ¹			0.47
III	4 (10)	1 (6.2)	
IV	36 (90)	15 (93.6)	
Gastric cancer			
Chemotherapy	19 (73.1)	3 (33.3)	0.03
Covered stent	16 (61.5)	5 (55.6)	0.75
CEA (ng/mL)	44.6 ± 138.3	5.7 ± 6.9	0.44
Pancreatic cancer,			
Chemotherapy	10 (71.4)	5 (71.4)	1.00
Covered stent	5 (35.7)	1 (14.3)	0.30
CEA (ng/mL)	7.0 ± 7.1	4.4 ± 4.9	0.42
CA 19-9 (IU/mL)	24.597 ± 73.120	1.731 ± 2.484	0.46
Location of obstruction			0.57
Gastric body	4 (10)	1 (6.2)	
Pylorus	22 (55)	7 (43.8)	
Duodenum	14 (35)	8 (50)	

¹Staged using the seventh edition of the tumor-node-metastasis classification system developed by the Union for International Cancer Control and the American Joint Committee on Cancer. Data are reported as the mean ± SD or *n* (%), as appropriate. CEA: Carcinoembryonic antigen; CA: Carbohydrate antigen; SD: Standard deviation.

with stent patency (Table 3). The results indicated that CEA level and chemotherapy were independent predictive factors for the duration of stent patency. When the CEA level was higher than 6 ng/mL at the time of stent placement, stent patency decreased [*P* = 0.006; adjusted hazard ratio (aHR) = 2.92, 95%CI: 1.36-6.25] (Figure 5). Palliative chemotherapy was statistically associated with an increase in stent patency (*P* = 0.009; aHR = 0.27, 95%CI: 0.10-0.72). The chemotherapy response rate was 63.6% in the stent dysfunction group, and 33.3% of the patients died without stent dysfunction. When we analyzed the cohort that underwent chemotherapy separately, a Cox proportional hazards model showed that longer stent patency might be associated with responding to first-line chemotherapy (*P* = 0.05; aHR = 0.38, 95%CI: 0.14-1.02).

DISCUSSION

In recent years, SEMS deployment has progressively replaced surgical gastrojejunostomy for the treatment of malignant gastroduodenal obstruction. Tringali *et al.*^[24] conducted a prospective multicenter study that

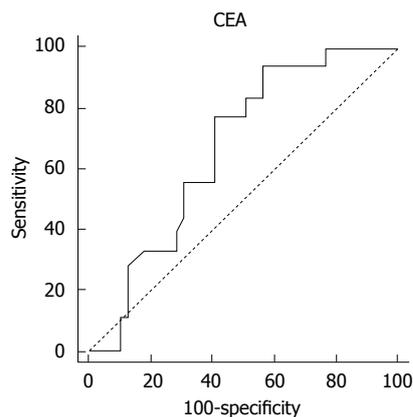


Figure 3 Receiver operating characteristic curve of the carcinoembryonic antigen level for predicting stent patency. ROC: Receiver operating characteristic; CEA: Carcinoembryonic antigen.

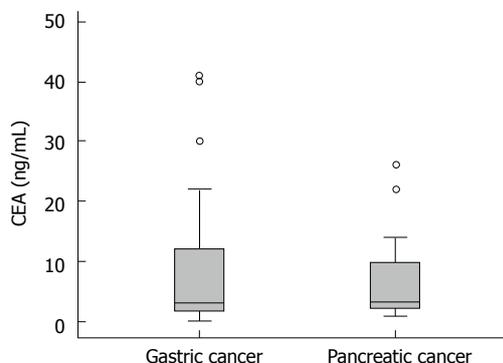


Figure 4 Comparison of carcinoembryonic antigen levels based on the type of malignancy. CEA: Carcinoembryonic antigen.

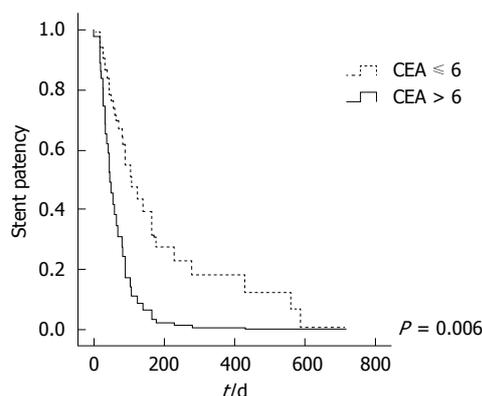


Figure 5 Stent patency rate according to carcinoembryonic antigen level. CEA: Carcinoembryonic antigen.

involved 108 patients with malignant gastroduodenal obstruction who were treated with SEMS and reported a technical success rate of 99.1% and clinical success rate of 87.6%. A meta-analysis of treatment using stents vs surgical gastrojejunostomy published in 2010 by Ly *et al.*^[25] showed that endoscopic stenting was associated with an increase in oral intake tolerability, shorter time to the initiation of oral intake, and shorter hospital stays after the procedure.

Table 3 Factors associated with stent patency in Cox proportional hazards models

	HR	95%CI	P value
Age	0.99	0.96-1.02	0.604
Sex (male)	2.02	0.94-4.30	0.068
CEA > 6 ng/mL	2.92	1.36-6.25	0.006
WHO score	3.73	1.35-10.31	0.011
Palliative chemotherapy	0.27	0.10-0.72	0.009
Covered stent	2.20	1.06-4.57	0.034
Carcinoma peritonei	2.64	1.16-6.02	0.020

CEA: Carcinoembryonic antigen; WHO: World Health Organization.

However, debate remains about what is the most suitable treatment approach for patients who have inoperable malignant gastroduodenal obstruction. In general, SEMS deployment is the preferred treatment option for patients who have short life expectancies^[26]. However, it is difficult to develop a therapeutic algorithm because the treatment method should be tailored according to disease status and patient preference. Although SEMS deployment is the preferred treatment modality and promptly relieves the symptoms associated with malignant gastroduodenal obstruction, stent-related adverse events may occur^[24]. Thus, it is important to be able to predict stent patency within the clinical context of inoperable malignant gastroduodenal obstruction.

There is a growing need to identify factors that can predict stent patency. A few studies that have investigated the factors that may affect SEMS patency following insertion have been published. Telford *et al.*^[11] reported that chemotherapy after stent insertion is significantly associated with the prolongation of oral intake (aHR = 0.41, 95%CI: 0.23-0.72). This was the first study to assess the prognostic factors that affect stent patency in the treatment of inoperable malignant gastroduodenal obstruction through stent insertion. Since then, other studies^[12,14,17] have reported similar results following the use of chemotherapy. In addition to chemotherapy, the stent type and the type of malignant obstructive lesion have been proposed as possible prognostic factors for stent patency^[15,17]; however, these results remain controversial. Some studies have reported that chemotherapy has no effect on stent patency in the treatment of malignant gastroduodenal obstruction through stent insertion^[15,27,28]. Other studies have reported that stent type and the type of malignant obstructive lesion have no significant associations with stent patency^[19,28,29]. Consequently, this is an important subject for further investigation.

Similar to results found in previous studies, this study showed an increase in stent patency in patients who underwent chemotherapy. Performing chemotherapy after stent insertion may reduce or stabilize the tumor burden and diminish tumor growth through the mesh of the stent or overgrowth at the edges of the stent. Kim *et al.*^[14] reported first-line chemotherapy to be a significant protective factor

against restenosis, which is comparable to our findings.

In addition, the type of malignant obstructive lesion and the type of stent used were not statistically associated with stent patency in our study. Stent migration occurred in two patients who underwent chemotherapy and had covered stents implanted. Previous studies have found that covered stents and undergoing chemotherapy are significant risk factors for stent migration^[14,17,19]. The reduction in tumor size caused by chemotherapy could lead to unintentional consequences for patients who receive covered stents because of the increased risk of stent migration.

This study found that peritoneal carcinomatosis and a poor performance status in patients were associated with reductions in stent patency. Documented peritoneal carcinomatosis has been considered a relative contraindication for stent placement^[30]. Although another study found that carcinomatosis does not adversely affect stent patency^[31], peritoneal seeding should be considered a possible risk for multifocal obstruction. In the same context, the poor performance status of a patient could adversely affect stent patency and could be associated with the systemic effects of the tumor.

In this study, CEA level was found to be a potential novel predictive factor of stent patency in the treatment of inoperable malignant gastroduodenal obstruction through stent insertion. CEA is a commonly used tumor marker and has been found to increase in the serum of patients with colorectal carcinomas, gastric carcinomas, pancreatic carcinomas, and other malignancies^[18]. CEA level has been shown to be independently associated with prognosis and survival in advanced gastric cancer^[32]. In addition, previous studies have demonstrated a significant association between CEA level and the prognosis of advanced pancreatic cancer^[33,34]. We performed an analysis that evaluated CEA as a potential predictive factor of stent patency and found that the stent patency rate in patients who had CEA levels > 6 ng/mL was lower than the rate in patients with lower CEA levels. This result suggests that CEA level could be a valuable predictive factor that is independently associated with stent patency in the palliative treatment of inoperable malignant gastroduodenal obstruction through stent insertion. CEA level could predict the prognosis of periampullary cancer as well as the patency of stents inserted for the palliation of malignant gastroduodenal obstruction. Given that prognostic factors are scarce and no serum markers for stent patency exist, the efficacy of CEA as an easily measurable predictive factor of stent patency that was demonstrated in this study is noteworthy. This study is the first to report CEA as a predictive factor of stent patency in the treatment of inoperable malignant gastroduodenal obstruction through stent insertion.

This study has limitations including its single-center, retrospective design and small sample size. However, we investigated sequential patients who had stents inserted for the treatment of malignant gastroduodenal

obstruction in our endoscopy unit, and we only enrolled patients who met the inclusion criteria. In addition, the treatment courses were regulated for all patients, which may lessen the limitations associated with the retrospective design of the study.

In conclusion, SEMS placement is an effective palliative treatment in patients who have inoperable malignant gastroduodenal obstruction. The level of serum CEA, which can be easily measured, was found to be associated with stent patency in the treatment of malignant gastroduodenal obstruction through stent insertion; thus, CEA level may be an effective predictor of stent patency. After receiving stents, patients with a CEA level > 6 ng/mL could be candidates for short-term follow-up using esophagogastroduodenoscopy within a few months. Through this strategy, physicians could help patients in the determination of appropriate treatment decisions, including, for example, preventing additional stenting before restenosis, and, consequently, they can help reduce patient suffering and re-hospitalization.

COMMENTS

Background

Self-expandable metallic stents (SEMS) are used as an effective palliative therapy in inoperable malignant gastroduodenal obstruction. However, clinical parameters associated with stent patency have been controversial, and no serum markers currently exist to help determine whether stent insertion may be an appropriate treatment.

Research frontiers

It is important to be able to predict stent patency within the clinical context of inoperable malignant gastroduodenal obstruction. This study assessed the efficacy of SEMS and possible predictive factors of stent patency in the palliative therapy of malignant gastroduodenal obstruction.

Innovations and breakthroughs

The present study showed that carcinoembryonic antigen (CEA) may be a novel predictive factor of stent patency in the palliative treatment of inoperable malignant gastroduodenal obstruction through stent insertion.

Applications

The authors could predict the stent prognosis using CEA levels. After performing stent placement, the patients with CEA levels greater than 6 could be candidates for short-term esophagogastroduodenoscopy follow-up.

Terminology

CEA is a frequently used tumor marker, and its levels are usually elevated in the serum of patients who have colorectal carcinomas, gastric carcinomas, and pancreatic carcinomas.

Peer-review

This is an interesting study, about possible predictors of the patency of self-expandable metallic stents in malignant gastroduodenal obstruction. It is well designed, well written and has an interesting discussion. CEA levels can easily be measured everywhere and this is a useful addition to the treatment of these patients.

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