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BRIEF ARTICLE

Temporary self-expanding metallic stents for achalasia: A prospective study with a long-term follow-up

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Abstract

AIM: To compare the efficacy of self-expanding metallic stents (SEMSs) for the long-term clinical treatment of achalasia.

METHODS: Ninety achalasic patients were treated with a temporary SEMS with a diameter of 20 mm (n = 30, group A), 25 mm (n = 30, group B) or 30 mm (n = 30, group C). Data on clinical symptoms, complications and treatment outcomes were collected, and follow-up was made at 6 mo and at 1, 3-5, 5-8, 8-10 and > 10 years, postoperatively.

RESULTS: Stent placement was successful in all patients. Although chest pain occurrence was high, stent migration was less in group C than in groups A and B. The clinical remission rate at 5-8, 8-10 and > 10 years in group C was higher than that in the other two groups. The treatment failure rate was lower in group C (13%) than in groups A (53%) and B (27%). SEMSs in group C resulted in reduced dysphagia scores and lowered esophageal sphincter pressures, as well as normal levels of barium height and width during all the follow-up time periods. Conversely, these parameters increased over time in groups A and B. The primary patency in group C was longer than in groups A and B.

CONCLUSION: A temporary SEMS with a diameter of 30 mm is associated with a superior long-term clinical efficacy in the treatment of achalasia compared with a SEMS with a diameter of 20 mm or 25 mm.

Key words: Achalasia; Dysphagia; Self-expanding metallic stents; Comparison

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INTRODUCTION

Self-expanding metallic stents (SEMSs), bare or covered,

have been used safely and effectively in the treatment of malignant esophageal dysphagia and fistula for the last two decades[1-6]. However, the management of benign esophageal strictures with stent placement has not been well established primarily due to complications, such as stent migration, reflux, perforation, bleeding, and most importantly, the development of new strictures as a result of stent-induced tissue hyperplasia[7-12].

Recently, a novel strategy using retrievable stents has been successfully applied in the treatment of benign esophageal strictures[7-10]. Temporary stent placement also seems to be an alternative approach for the treatment of patients with esophageal achalasia. However, there are only a few reports of this disease being treated with SEMSs[11-19]. Commencing in July 1994, we designed and manufactured (Youyan Yijin Advanced Materials Co. Ltd, Beijing, China) a temporary SEMS using three diameters specialized for the treatment of esophageal achalasia[13-16,20]. Because relatively little is known about the long-term efficacy of patients treated with SEMS, we designed a prospective study to compare the long-term clinical outcome of the stents with different diameters in the treatment of achalasic patients.

MATERIALS AND METHODS

Study design

This pilot study was approved by the Institutional Review Board of the Sixth Affiliated People's Hospital of Shanghai Jiao Tong University, and informed consent was obtained from each patient. From July 1994 to December 2007, 90 consecutive achalasic patients were treated with temporary SEMSs with a diameter of 20 mm (n = 30, group A), 25 mm (n = 30, group B) or 30 mm (n = 30, group C). Patients with achalasia agreed to undergo a prospective study to evaluate the use of fluoroscopically-placed SEMS over a 13-year follow-up period. The preoperative diagnosis was based on clinical presentations, barium swallows, gastroscopies or esophageal manometric.

The inclusion criteria for stent placement were as follows: (1) documented primary esophageal achalasia; (2) recurrent dysphagia following pneumatic balloon dilation; and (3) patient life expectancy of more than 6 mo. The exclusion criteria were (1) a lesion longer than 6 cm; (2) dysfunction of blood coagulation, active infection, significant cardiac or pulmonary disease, malignancy, and significant psychological or psychosocial dysfunction; and (3) World Health Organization performance score ≥ 3. The preoperative dysphagia scores were evaluated by three radiologists, including grade 0, no dysphagia; grade 1, some solid food; grade 2, liquids only; grade 3, difficulty with liquids and saliva; grade 4, complete dysphagia. These procedures were performed by an interventional radiologist (Cheng YS) who has 15 years of experience in gastrointestinal interventional radiology.

Stent construction and insertion procedure

Each SEMS was woven from a single thread of 0.16 mm highly elastic nitinol wire. As shown in Figure 1, the stent had a tubular configuration with an elliptical structure, proximally and distally. The body of the stent was covered with polyethylene measuring 20, 25 or 30 mm in diameter and 80 mm in length when fully expanded. The elliptic structure at both ends was 1 cm in length and 2 mm larger in diameter than the body of the stent. For implantation under fluoroscopic guidance, each stent was compressively mounted on a guiding tube by a 24-French (Fr) introducer sheath (8 mm in diameter).

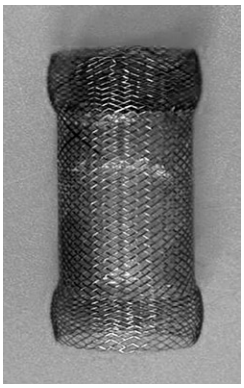

Figure 1 Photograph of a partially covered self-expanding metallic stent.

The SEMSs were specifically designed for placement in the esophageal cardia. The details of the stent placement techniques are described elsewhere[20]. Briefly, after topical anesthesia, a 0.035-inch guide wire (Radiofocus M; Terumo, Tokyo, Japan) with a straight 5-Fr catheter (Torcon NB; Cook, Bloomington, USA) was advanced perorally until the tip reached the gastric body, after which it was exchanged for a stiffer guide wire (0.035-inch Amplatz super-stiff). Under fluoroscopic control, a 24-Fr delivery system (Youyan Yijin, Beijing, China) was inserted over the guide wire until the proximal and distal edges of the stent bridged the esophageal achalasia. The stent was then deployed by withdrawing the introducer sheath. Patients ate semisolid food on the day following stent placement and were given a prophylactic H_2 receptor blockade to prevent reflux esophagitis. Chest radiography was performed 1, 3 and 7 d after the stent placement to verify the state of the stent expansion and migration.

Stent retrieval was performed by gastroscopy 4-5 d after placement. Ice-cold water (500-1000 mL) was injected *via* the bioptic hole to retract the stent, and the stent was gently removed by grasping the proximal wire or by using a retrieval lasso. Usually less than 10 min were required for this procedure.

Postoperative outcome evaluations

Postoperative outcomes were assessed by responses to a standardized questionnaire for symptoms at the initial presentation and during the follow-up periods. In the questionnaire, the clinical symptoms were recorded, including those of dysphagia score, chest pain, barium swallow, esophageal emptying, esophageal manometry and, if necessary, endoscopy. Outcome assessments were performed postoperatively at 6 mo and at 1, 3-5, 5-8, 8-10 and > 10 years. A slightly modified grading system of Vantrappen and Hellemans[21] was used to estimate the effectiveness of

treatment, including: (1) excellent, completely free of symptoms; (2) good, dysphagia or chest pain ⩽ once per week without regurgitation; (3) moderate, dysphagia 2-4 times per week; and (4) poor, dysphagia daily and/or regurgitation. Ratings of excellent and good were considered as an indication of treatment success, and ratings of moderate and poor were an indication of treatment failure.

Timed barium esophagram

Details of the timed barium esophagram[22,23] as an objective assessment of esophageal emptying were as previously described. Briefly, after fasting overnight, patients ingested a low density barium sulfate suspension (45% w/v) for 30-45 s while maintaining an upright position. Patients were instructed to drink the amount of barium they could tolerate without regurgitation or aspiration (usually between 100 and 250 mL). With the patient upright in a slightly left posterior oblique position, radiographs of the esophagus were taken at 1, 2 and 5 min after the last swallow of barium. The maximal esophageal width (barium width) and the distance from the distal esophagus (identified by a bird's beak appearance of the esophagogastric junction) to the top of a distinct barium column (barium height) were measured. The same volume of barium was given to each patient for both the preoperative and postoperative studies. The 5 min barium heights and widths (normal ⩽ 3 cm) were used for analysis of the degree of esophageal emptying and of reduction in esophageal diameter. In most normal subjects, barium could be completely emptied out of the esophagus by 1 min, and emptied from all individuals by 5 min.

Esophageal manometry

Esophageal manometry was performed in all patients with an overnight fast using a low compliance, pneumohydraulic water infusion system (Arndofer, Medical Specialties, Milwaukee, WI, USA) and an 8-lumen, manometric catheter. The catheter had four ports radially oriented (90°) near the tip and four centrally positioned 5 cm apart (5, 10, 15 and 20 cm from the tip). The recording sites were connected to an 8-channel polygraph (Synetics Medical AB, Stockholm, Sweden). The manometric catheter assembly was passed transnasally without any sedation into the stomach. The lower esophageal sphincter (LES) pressure was determined using the station pull through technique and recorded as the mean of four measurements at mid-respiration. Completeness of LES relaxation (normal > 85%) was assessed as the percent decrease from the resting LES pressure to the gastric baseline following wet swallows. Esophageal body motility was recorded at 3, 8, 13 and 18 cm above the LES in response to 5 mL swallows of water at 30 s intervals[24]. LES pressures and peristalsis were determined at the time of diagnosis, at 6 mo, and 1, 3-5, 5-8, 8-10 and > 10 years after the procedures.

Statistical analysis

All the data were expressed as the mean ± SD. Comparisons of the variables between the two groups were performed by the Mann-Whitney test, χ^2 test or the Fisher's exact test as appropriate. The cumulative remission rate was determined by the Kaplan-Meier estimator and the difference between their curves was tested by the log rank test. Statistical analyses were performed using SPSS statistical software (version 13.0 for Windows, SPSS Inc., Chicago, IL, USA). The *P* value was considered statistically significant if ⩽ 0.05.

Table 1 Clinical characteristics of 90 patients treated with a temporary self-expanding metallic stent with a diameter of 20, 25, or 30 mm (mean ± SD) *n* (%)

	Group A (*n* = 30)	Group B (*n* = 30)	Group C (*n* = 30)	*P* value
Age (yr)	43.37 ± 15.84	36.23 ± 10.58	37.30 ± 13.13	> 0.05
Gender (M/F)	16/14	17/13	18/12	> 0.05
Duration of symptoms	6.01 ± 3.69	4.74 ± 2.76	5.33 ± 3.65	> 0.05
Symptoms				
Chest pain	23 (77)	21 (70)	18 (60)	> 0.05
Regurgitation	15 (50)	12 (40)	15 (50)	> 0.05
Heartburn	7 (23)	9 (30)	10 (33)	> 0.05
Weight loss	3.80 ± 2.90	2.96 ± 2.76	3.57 ± 3.36	> 0.05
Dysphagia score	2.93 ± 0.45	2.87 ± 0.43	2.83 ± 0.53	> 0.05
Lesion diameter (mm)	5.33 ± 2.14	5.97 ± 1.90	6.0 ± 2.38	> 0.05
Lesion length (mm)	16.93 ± 6.50	19.73 ± 5.98	18.57 ± 6.52	> 0.05

RESULTS

Clinical characteristics

The clinical characteristics of the patient population are summarized in Table 1. A total of 90 patients who underwent stent placement for achalasia were enrolled in this prospective analysis. These included 51 men and 39 women with a mean age of 37.96 ± 13.32 years (range: 11-85 years). The mean duration of the symptoms between a significant dysphagia confirmation and stent placement was 5.36 ± 3.39 years (range: 1.1-15.7 years). There were no significant differences among the three groups in clinical symptoms, duration of the symptoms, lesion diameter, lesion length or the length of the stent (Table 1).

Technical and initial clinical outcomes

Technical and initial clinical outcomes among the three groups are shown in Table 2. Fluoroscopic stent placement in the esophageal cardiac gland was technically successful in all patients without procedure-related complications. Complete expansion of the stent occurred within 24 h after placement. The mean time of the procedure was 19 ± 6 min (range: 10-30 min).

Stent migration was significantly less in group C than in group A ($P = 0.039$), whereas chest pain occurrence was significantly higher in group C than in group A ($P = 0.0047$). There were no significant differences in reflux, bleeding or food impaction among the three groups ($P > 0.05$). No perforation occurred among the three groups after stent placement, and the 30-d mortality was nil.

Table 2 Technical and clinical outcome among the three groups (mean ± SD) *n* (%)

	Group A (*n* = 30)	Group B (*n* = 30)	Group C (*n* = 30)	*P* value
Early outcome				
Technique success	100%	100%	100%	1.0
Complications				
Stent migration	8 (27)	4 (13)	2 (7)[a] (*P* = 0.039)	0.096
Chest pain	5 (17)	10 (33)	12 (40)[a] (*P* = 0.047)	0.130
Reflux	7 (23)	5 (17)	6 (20)	0.814
Bleeding	3 (10)	5 (23)	6 (20)	0.557
Perforation	0	0	0	1.0
Food impaction	2 (7)	0	0	0.132
30-d mortality	0	0	0	1.0
Late outcome				
Primary patency (yr)	5.45 ± 0.41	6.67 ± 0.56[c] (*P* = 0.023)	7.15 ± 0.50[a] (*P* = 0.003)	0.006
Cumulative treatment failures	16 (53)	8 (27)[c] (*P* = 0.037)	4 (13)[a] (*P* = 0.001)	0.003
Follow-up (yr)	7.13 ± 2.61	7.24 ± 2.95	7.30 ± 2.46	0.997

[a]*P* < 0.05, Group C *vs* Group A; [c]*P* < 0.05, Group B *vs* Group A.

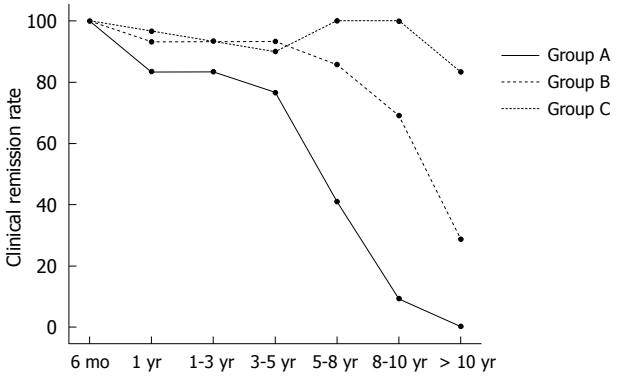

Figure 2 Clinical remission rates in comparison with self-expanding metallic stents with a diameter of 30 mm (Group C), 25 mm (Group B) or 20 mm (Group A).

Treatment success was achieved in all patients with a patency of the esophageal cardiac gland at 1 mo after stent removal, and the dysphagia scores significantly improved for all patients. There were no significant differences in clinical success among the three groups ($P > 0.05$).

Long-term follow-up and final outcomes

Figure 2 shows the long-term follow-up and clinical outcomes at various follow-up periods and the curves of the clinical remission rates among the groups. The mean time from stent removal to the last follow-up assessment was 7.23 ± 2.65 years (range: 3-12.7 years). All patients were assessed at 6 mo and at 1, 1-3, 3-5, 5-8 (67 patients), 8-10 (38 patients) and > 10 years (19 patients), prospectively. There were no significant differences in these rates at 6 mo or at 1, 1-3 or 3-5 years among the three groups ($P > 0.05$). However, the clinical remission rates were significantly higher in group C than in groups A and B at 5-8, 8-10 and > 10 years (Figure 2).

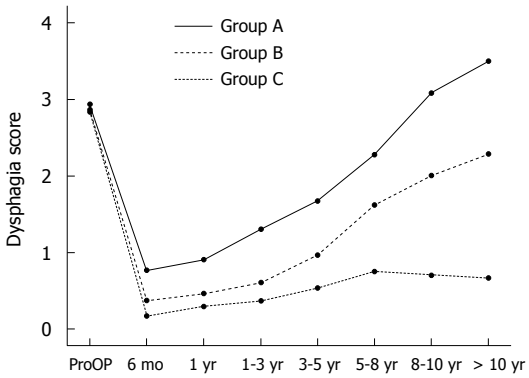

Figure 3 Dysphagia scores among the three groups before self-expanding metallic stents placement at different follow-up time intervals.

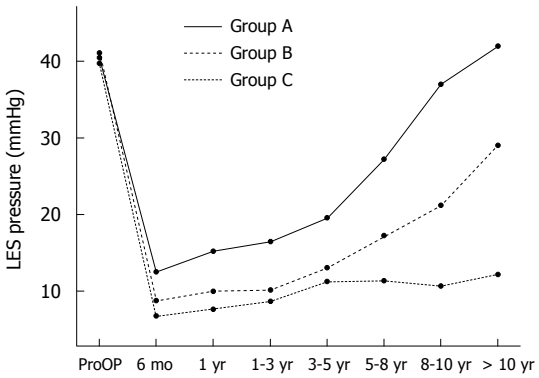

Figure 4 Lower esophageal sphincter pressures assessed by manometry among the three groups before self-expanding metallic stent placement at different follow-up time intervals. LES: Lower esophageal sphincter.

Figures 3-5 exhibit the curves of the dysphagia scores, the LES pressures and the barium height and width measurement among the three groups. The LES pressure was less than 12 mmHg in group C at all times of measurement. In group C, the esophageal barium height and diameter also remained consistently lower than the preoperative values and below normal levels. Similarly, the dysphagia score for group C remained at a lower level for all later measurements. Conversely, the dysphagia score, LES pressure and esophageal emptying (as assessed by the barium column length and width) in group A increased and gradually returned to the preoperative values. The same parameters in group B increased more slowly than those in group A. However, they were significantly increased at 8-10-year and > 10-year follow-up evaluations, although they remained below the preoperative values.

Within the 13-year follow-up period, the stent treatment was considered to have failed in 16 (53%) patients in group A, 8 (27%) in group B and 4 (13%) in group C after 5.53 ± 3.74 years (range: 7 mo-12.7 years). The overall cumulative treatment failure rate was significantly higher in group A than in groups B and C ($P = 0.0037$ and $P = 0.0001$). Nine patients with poor clinical results (seven in group A and two in group B) after 8.28 ± 3.51 years (range: 3.1-11.4 years) received an additional stent treatment (diameter of 30 mm). Although they were considered as treat-

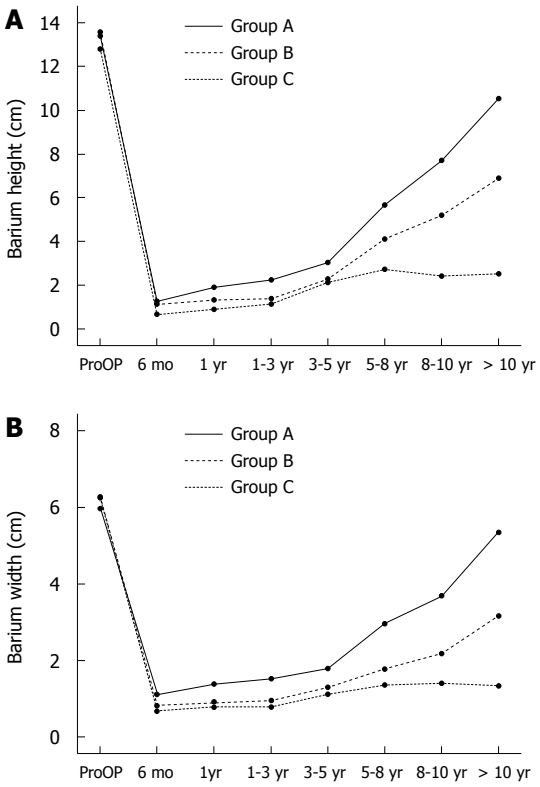

Figure 5 The barium height (A) and width (B) assessed by a timed barium esophagram among the three groups before self-expanding metallic stent placement at different follow-up time intervals.

ment failures, the remaining 19 patients were included in the follow-up assessments because they were experiencing mild recurrent dysphagia. One patient died at the end of this study due to old age.

The mean survival in groups A, B and C was 7.13 ± 0.48 years (95% CI: 6.19-8.06), 7.24 ± 0.54 years (95% CI: 6.19-8.30) and 7.31 ± 0.45 years (95% CI: 6.43-8.12), respectively; and the median survival was 6.60 ± 0.61 years (95% CI: 5.39-7.81), 6.90 ± 1.30 years (95% CI: 4.35-9.45), and 7.10 ± 0.61 years (95% CI: 5.89-8.31), respectively. There were no significant differences in patient survivals among the three groups ($P = 0.828 > 0.05$, log rank test). The primary patency in groups C and B was significantly longer than that in group A (Table 2, $P = 0.001$ and $P = 0.02$, log rank test).

DISCUSSION

In this prospective study, the overall cumulative clinical remission rate was 47%, 73% and 87% in groups A, B and C, respectively. This rate was significantly lower in group A than that in groups B and C, whereas the clinical remission rate at the > 10-year follow-up period in group C (83.3%) was substantially higher than that in groups B (28.6%) and A (0%). The curve of the clinical remission rate in group A dropped quickly from 100% at 6 mo to 0% at the > 10 years assessment, whereas the curve of the clinical remission rate in group C declined slowly from 100% at 6 mo to 83.3% at the > 10 years assessment. The curve of the clinical remission rate in group B fell between the curves of groups A and C (Figure 2). Notably, the mean primary patency in group C was longer than that in groups A and B. These results demonstrate that the clinical remission rate in group C was higher than in groups A and B over the long-term follow-up periods.

Moreover, SEMS treatment in group C resulted in a reduced dysphagia score and LES pressure, and normal levels of barium height and width during all follow-up time points, whereas these parameters increased and gradually returned to the preoperative values in group A. Although, these parameters increased more slowly in group B than in group A, they increased significantly at the 8-10-year and > 10-year follow-up evaluations. These results indicate a superior long-term effectiveness for the clinical symptomatic remission of esophageal achalasia in group C compared with groups A and B.

The data in group C demonstrated a successful long-term clinical remission rate comparable with the results of other published studies which required repeated pneumatic dilations[25-34], and our results were even better than previous reports of achalasic patients treated with SEMS placement[11,12,18,19]. Furthermore, the long-term efficacy of SEMSs with a diameter of 30 mm is comparable with those of laparoscopic esophageal myotomy, which results in a success rate of about 90% after a mean follow-up period of 5-14 years[35-39]. The higher long-term clinical remission rate in group C may be attributed to the use of a large-diameter SEMS. The stent expanded to its full size within 24 h after placement, and we believe that the radial expansile force was generated spontaneously, slowly and evenly during stent expansion. Unlike pneumatic dilation, which can tear the cardiac muscular acutely and suddenly, we speculate that the SEMS opened the cardiac musculature slowly and gently. Thus, it is likely that the cardia muscularis was separated evenly, resulting in less restenosis and a satisfactory long-term therapeutic efficacy.

In this study, we compared the long-term clinical outcome of the stent with different diameters placed once for the treatment of achalasic patients. The question remains if smaller stents for a different time frame can give the same results as short duration wider stents? According to our experience, the same result may not be obtained from the wider stent due to insufficient radial expansile force and enough time to tear cardiac musculature. Moreover, it is unlikely to be adopted by the patients due to repeated implants and retrieval procedures as well as a high cost.

Stent migration has been the most frequent complication in stent placement for benign strictures, ranging from 18.7%-81.8%[7,11,40,41]. As expected, the migration rate was lower in group C (6.6%) than in groups A (26.7%) and B (13.3%). These results indicate that as the diameter of the SEMS increases, the potential of stent migration may be reduced. We speculate that the large-sized SEMSs provided a substantial radial expansile force and friction (due to the uncovered nitinol-wire) against the esophageal wall, and the temporary stent placement prevented the risk of late migration. Notably, previous reports have confirmed

that SEMSs with larger diameters (generally ⩾ 25 mm) employed in the esophagus may minimize the risk of migration[7,11,40-42].

The present study had several limitations. First, this was a single center study with no control studies. Although a prospective study was applied to compare the efficacy of three different sized SEMSs, future randomized trials in the use of our stent and pneumatic dilation are needed to compare the long-term clinical efficacy, the risk of complications and recurrent dysphagia that are involved in the treatment of achalasia. Second, larger SEMS may result in a high rate of chest pain, bleeding and perforation, while small SEMS may lead to a high rate of stent migration and food impaction. In addition, regurgitation may occur after SEMS placement.

In conclusion, we found that a temporary SEMS, 30 mm in diameter, was associated with a superior long-term clinical efficacy for the treatment of achalasia compared with SEMSs with diameters of 20 or 25 mm. Randomized trials comparing temporary stent placement with pneumatic dilation are needed.

COMMENTS

Background

Retrievable self-expanding metallic stents (SEMSs) have been successfully applied in the treatment of benign esophageal strictures, but they are rarely used for the treatment of patients with esophageal achalasia.

Research frontiers

The authors designed temporary SEMSs for the treatment of patients with esophageal achalasia; however, little is known about the long-term efficacy in patients treated with SEMS. This prospective study compared the long-term clinical outcome of the stent with different diameters in the treatment of achalasic patients.

Innovations and breakthroughs

The authors designed and manufactured the temporary SEMSs of three diameters in size specialized for the treatment of patients with esophageal achalasia. The SEMSs were inserted under fluoroscopic control and retrieved by gastroscopy 4-5 d after placement. A temporary SEMS, 30 mm in diameter, was associated with a superior long-term clinical efficacy for the treatment of achalasia compared with SEMSs with diameters of 20 or 25 mm.

Applications

A temporary SEMS, 30 mm in diameter, was associated with a superior long-term clinical efficacy for the treatment of achalasia compared with SEMSs with diameters of 20 or 25 mm.

Terminology

Achalasia is a disorder of esophageal motility characterized by aperistalsis, elevated lower esophageal sphincter (LES) pressure, and failure of LES relaxation upon swallowing.

Peer review

This manuscript describes the effectiveness of LES dilation in patients with achalasia on placing a self-expanding metal stent. It is a well-written manuscript with a clear objective, although some gray-points were detected and could be discussed in order to improve the present version.

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