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ORIGINAL ARTICLE

Literature Analysis of the Treatment of Benign Esophageal Disease with Stent

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Abstract To analyze the efficacy and safety of benign esophageal disease used biodegradable (BD) stent or metal stent. The English literatures of benign esophageal disease that were treated by biodegradable or metal stents implantation were retrieved and summarized. In all 323 benign esophageal disease, the most common etiologies were benign refractory stricture, surgical anastomotic stricture and esophageal fistula/leak/perforation, but the main characteristics between the two groups were not significantly different. One hundred fifty-four cases were completely healed by using BD stents or self-expandable metal stents (SEMS) (47.7 %). Clinical success was achieved in 47.7 % of all patients and there was no significant difference between BD stents (51 %) and SEMS (46.2 %) (P=0.472), while stent migration occurred more frequently with SEMS (33.9 %) than with BD stent (19.6 %) ($P \leq 0.05$), and tissue in- or overgrowth occurred more frequently with SEMS (22.2 %) than with BD stents (8.8 %) ($P \leq 0.05$). Furthermore, the time about degradation of BD stents in esophageal was longer than removal of SEMS from the esophagus ($P \leq 0.05$). Placement of BD stents or SEMS provides effective and safe relief for benign esophageal disease. Clinical success and mortality were not significantly different. BD stents offers an advantage of fewer complications. Although stent placement is a viable strategy in patients with benign esophageal disease, the ideal treatment strategy and further randomized trials with large number of patients are needed.

Keywords Esophageal disease · Benign · Biodegradable stent · Metal stent

Abbreviations

BD stent	Biodegradable stents
SEMS	Self-expandable metal stents
FCSEMS	Fully covered self-expandable metal stent
SEPS	Self-expandable plastic stent
RBES (BRES)	Refractory benign esophageal strictures (benign refractory esophageal strictures)
PLLA	Poly-1actide-co-glycolic acid
BD SX-ELLA	the SX-ELLA biodegradable stents (ELLA-CS, Hradec Kralove, Czech Republic)
SD	Standard deviation

Introduction

Benign conditions of esophageal disease include refractory strictures, tracheoesophageal fistula, iatrogenic perforation, or leak. Temporary stent placement is increasingly used to treat a variety of benign esophageal disease. The benefits of esophageal stents are healing without diversion or reconstruction and early return to an oral diet, with minimal mortality and morbidity [1, 2]. Different types of stents have been evaluated for this purpose, included SEMS, SEPS, and most recently, biodegradable stents.

SEMS was initially developed approximately 20 years. A variety of modifications about stent design have been introduced. However, there are still drawbacks of stent placement such as migration, reflux esophagitis, and tumor ingrowth or overgrowth [3]. Especially, the drawback of SEMS is that the stents need to be removed, and it will be difficult sometimes.

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Table 1 Studies on the use of BD stents and metal stents in esophageal diseases

References	Year	Stent type	No. of patients	Category of esophageal disease	Follow up median (mouths)	Stent length, mm median/range	Technical success *n* (%)	Clinical success *n* (%)
Saito Y et al. [5]	2007	PLLA	13	Benign stricture	12	–	13 (100)	13 (100)
Repici A et al. [6]	2010	BD SX-ELLA	21	RBES	12	60–135	21 (100)	9 (42.9)
van Hooft JE et al. [7]	2011	BD SX-ELLA	10	Esophagogastric anastomotic strictures	6	60	10 (100)	6 (60)
Cerna M et al. [8]	2011	Covered BD SX-ELLA	5	Esophagogastric leaks or perforations	12	115	5 (100)	4 (80)
Van Boeckel PG et al. [9]	2011	BD SX-ELLA	18	RBES	5	60–135	16 (85)	6 (33.3)
Griffiths EA et al. [10]	2012	BD SX-ELLA	7	Benign and malignant strictures	5	60–115	7 (100)	5 (71.4)
Hirdes MM et al. [11]	2012	BD SX-ELLA	28	RBES	24	60–135	26 (93)	9 (32.1)
Kim JH et al. [12]	2009	Metallic stent	55	RBES	36	–	55 (100)	18 (32.7)
Bakken JC et al. [13]	2010	FCSEMS	56	Esophageal fistula/leak and Esophageal perforation and stricture	5	70–120	52 (93)	26 (44.1)
Senousy BE et al. [14]	2010	FCSEMS	14	Esophageal fistula and benign strictures	6	–	14 (100)	12 (85.7)
Eloubeidi MA et al. [15]	2011	FCSEMS	35	Benign esophageal strictures and leaks/perforations	–	70–120	35 (100)	11 (31.4)
Hirdes MM et al. [16]	2012	FCSEMS	15	RBES	–	–	13 (86.7)	0 (0)
Liu J et al. [17]	2012	FCSEMS	24	RBES	–	55–120	24 (100)	18 (75)
Schweigert M et al. [18]	2013	SEMS or silicone stent	22	anastomotic leakage	2	–	17 (77.3)	17 (77.3) (2 died)

PLLA poly-1actide-co-glycolic acid, *BD stent* biodegradable stents, *SEMS* self-expandable metal stents, *FCSEMS* fully covered self-expandable metal stent, *SEPS* self-expandable plastic stent, *RBES* refractory benign esophageal strictures (benign refractory esophageal strictures), *BD SX-ELLA* the SX-ELLA biodegradable stents (ELLA-CS, Hradec Kralove, Czech Republic)

An alternative for esophageal stents is the recently introduced BD stents. BD stents have been developed to overcome some of the problems encountered with SEMS. It was metabolized and eventually absorbed by the body. Therefore, it has an advantage that stent removal is not required. The main indication of BD stents includes treatment of benign esophageal disease, since it does not require endoscopic removal [4].

But there are few studies that compared clinical efficacy and safety of SEMS and BD stents. The favorable choice for benign esophageal disease is still no definite answer. We therefore performed a systematic review of the currently available literature to evaluate clinical efficacy and safety of treating benign esophageal disease with different stent designs (SEMS and BD stents).

Materials and Methods

Search Method

Studies were identified by searching CBMDISC, MEDLARS on line (Medline), PUBMED, Springer, Web of Science (SCI), etc. within a date range from Aug. 2007 to Aug. 2013. Each search was performed for studies in the English language and limited to humans. Search strategies were as follows: stents and benign esophageal disease OR refractory strictures OR tracheoesophageal fistula OR iatrogenic perforation or leak. Retrieval resource included Tongji University library and network resources.

Literature Search

All the relevant literatures were retrieved by the above method. Then, a scan of the reference lists of each article was undertaken to identify other relevant articles that were missed in the search. Studies that met the following inclusion criteria were selected: (1) patients with benign esophageal disease; (2) endoscopic stent placement; (3) the participants in the study were humans; and (4) results on a specific stent design (SEMS, FSEMS, PSEMS, PLLA, and BD SX-ELLA). Studies that were in the non-English language, case reports, letters, reviews, editorials, and studies in patients with a malignant indication for stent placement were excluded.

In our paper, we did a study comparing BD stent with SEMS and excluded SEPS mainly based on the three points: (1) the main treatment of benign esophageal disease with stents is SEMS and BD stents; (2) we retrieved few relevant literatures for the plastic stents in recent years that we are unable to complete the effective statistical analysis; (3) SEPS has been rarely used in clinic due to the high rates of some complications of SEPS and the limitation of materials' own attribute.

Table 2 Etiology for stent placement in benign esophageal diseases

Etiology		Patients	%
RBES	Etiology unknown	29	9.0
	Radiation-induced stricture	21	6.5
	Surgical anastomotic stricture	84	26.0
	Peptic stricture	83	25.7
	Fibrosis	3	0.9
	Pill induced	1	0.3
	Post-necrotizing esophagitis	1	0.3
	Sclerotherapy	1	0.3
	Barrett's related stricture	1	0.3
	Latrogenic	1	0.3
	Following ischemic esophagitis	2	0.6
	Lichen planus	1	0.3
	Achalasia	2	0.6
	Following multiple stent placements	1	0.3
	Total	231	71.5
Esophageal perforation/leak	Esophageal perforation	14	4.3
	Esophageal fistula/leak	68	21.1
	Boerhaave's syndrome	3	0.9
	Total	85	26.3
Unknown		7	2.2
Total		323	100

RBES refractory benign esophageal strictures (benign refractory esophageal strictures)

One hundred twenty-eight articles in databases were detected. Of these, 14 articles met our inclusion criteria for the pooled analysis (Table 1). A total of seven studies reported results on BD stent placement [5–11], seven on SEMS placement for the treatment of benign esophageal disease [12–18].

Date Abstraction

Date on year of publication, first author, title, stent type, total number of patients included, category of esophageal disease, and outcome of the study were extracted. All abstracts and titles of studies were screened.

Statistical Analysis

After data extraction, data were pooled according to stent design. Data comparison between the different stent designs was performed using chi-squared test and Mann-Whitney test. A P value<0.05 was considered statistically significant. Statistical analyses were conducted using SPSS version 17.0.

Results

All studies were published between Aug. 2007 and Aug. 2013. Fourteen studies evaluated 323 patients with completed follow-

Table 3 Pooled analysis of outcome of studies reporting on BD stent and SEMS placement for benign esophageal diseases

Characteristics	BD stents	SEMS	P value
Age (years), mean±SD (range)	61.2±3.8 (10–88)	58.9±5.5 (1–94)	0.848
Gender, *n* (%)	102 (31.6)	221 (68.4)	0.128
Male, *n* (%)	63 (19.5)	113 (35.0)	
Female, *n* (%)	32 (9.9)	86 (26.2)	
Unknown, *n*	7	22	
Dilation before stent placement, *n* (%)	54 (16.7)	140 (43.3)	0.108
Missing, *n* (%)	13 (4.0)	22 (6.8)	
Main indication for stent placement			
Benign refractory stricture, *n* (%)	91 (28.2)	118 (36.5)	1.000
Fistula/leakages/perforations, *n* (%)	8 (2.5)	76 (23.5)	
Unknown, *n*	7		
Technical success, *n* (%)	98 (96.1)	210 (95.0)	0.074
Clinical success, *n* (%)	52 (51.0)	102 (46.2)	0.472
Benign refractory stricture, *n* (%)	42 (41.2)	46 (20.8)	
Fistula/leakages/perforations, *n* (%)	6 (5.9)	26 (11.8)	
Unknown, *n*	0	7	
Failure, *n* (%)	50 (49.0)	119 (53.8)	
Mortality, *n* (%)	9 (8.8)	2 (0.9)	0.262
Stent related	1	0	
Cardiac disease	3	0	
Cancer	3	0	
Aspiration pneumonia	1	0	
Severe persisting sepsis	0	2	
Unknown	1	0	
Time stent in place (days)	84	49	0.007
Stent characteristics			
Stent length, mm	95.8±18.6	105±10.0	
Median (range)	(60–135)	(55–150)	
Stent diameter, mm	25.7±2.0	22.3±1.8	
Median (range)	(18–31)	(18–28)	
Re-intervention, *n* (%)	42 (41.2)	92 (41.6)	0.042
Main complications, *n* (%)	12 (11.8)	20 (9.0)	0.436
Migration, *n* (%)	20 (19.6)	75 (33.9)	0.021
Tissue growth, *n* (%)	9 (8.8)	49 (22.2)	0.039

SD standard deviation

up, of whom 102 were treated with BD stents and 221 were treated with SEMS. Overall, 176 (54.5 %) patients were male, 118 (36.5 %) patients were female, and 29 other patients' gender was unknown.

The etiologies of benign esophageal disease were divided into two kinds: RBES and esophageal perforation/leak. Etiology for stent placement was shown in Table 3. There were 231 (71.5 %) patients with RBES, 85 (26.3 %) patients with esophageal perforation/leak, and the remaining 7 (2.2 %) patients with other unknown etiologies (Table 2).

Stent placement outcomes are shown in Table 3. Clinical success (no patients died and no severe life-threatening complications occurred in post operation) was achieved in 47.7 % of all patients and was not significantly different between BD stents (51 %) and SEMS (46.2 %) (P=0.472). The overall technical success rate of stent placement was 95.4 %, more often with BD stent [n=98 (96.1 %)] than with SEMS [n=210 (95.0 %)] (P=0.074), but there was no significant difference. Re-intervention for incomplete sealing was performed more with SEMS [n=92 (41.6 %)] than with BD stents [n=42 (41.2 %)] ($P\leq0.05$), but the difference between the two groups is not significant.

Mortality was 3.4 % in all patients, and there was no significant difference between the two groups. Reasons of death for some patients were cardiac disease (n=3), aspiration pneumonia (n=1), and severe persisting sepsis (n=2). Another three patients died of metastasized renal cell cancer, colorectal cancer, and adenocarcinoma without extrinsic esophageal compression, respectively. And one patient's death was unknown. Only one patient death was associated with stent.

Thirty-two (9.9 %) patients had main complications (severe life-threatening complications) [BD stent (n=12) and SEMS (n=20)], and there was no significant difference between different stent types (P=0.436). Stent migration occurred more often with SEMS [n=75 (33.9 %)] than with BD stents [n=20 (19.6 %)] ($P\leq0.05$), and tissue in- or overgrowth occurred more often with SEMS [n=49 (22.2 %)] than with BD stent [n=9 (8.8 %)] ($P\leq0.05$).

Subgroup analysis for BRES was performed (Table 4). Tissue in- or overgrowth occurred more often with SEMS [n=24 (20.3 %)] than with BD stent [n=9 (9.9 %)] ($P\leq0.05$). Stent migration was more significantly occurred with SEMS (16.9 %) compared with BD stent (7.7 %) ($P<0.05$). No significant differences were found between BD stents and SEMS for the following variables: clinical success, technical success, re-intervention, and main complications (Fig. 1).

Another subgroup analysis for esophageal fistula/leakage/perforation was unfinished completely by a lack of quantitative data. Nevertheless, there is a statistical significance between BD stent and SEMS for technical success ($P<0.05$). In contrast to that clinical success is not significantly different between the two groups. And regretfully, we don't know the partial data about the following variables: re-intervention, main complications, migration, and tissue growth.

Table 4 Outcome of 91 patients treated with a BD stent and 118 patients treated with an SEMS for RBES

Characteristics	BD stents	SEMS	P value
Age (years), mean±SD (range)	61.4±4.1 (15–88)	57.9±5.3 (1–94)	0.470
Gender, n (%)	91 (28.2)	118 (36.5)	1.000
Male, n (%)	51 (56.0)	46 (39.0)	
Female, n (%)	33 (36.3)	48 (40.7)	
Unknown, n	7	24	
Dilation before stent placement, n (%)	53 (58.2)	94 (79.7)	0.199
Unknown, n	7	24	
Technical success, n (%)	87 (95.6)	116 (98.3)	0.170
Clinical success, n (%)	42 (46.2)	46 (44.2)	0.833
Unknown, n	0	7	
Failure, n (%)	49 (53.9)	65 (55.1)	
Time stent in place (days)	84	49	0.025
Stent characteristics			
Stent length, mm	60.0±1.2	101.3±14.4	
Median (range)	(60–135)	(55–150)	
Stent diameter, mm	25.8±2.2	21.2±1.6	
Median (range)	(18–31)	(18–28)	
Re-intervention, n (%)	41 (45.1)	51 (43.2)	0.078
Main complications, n (%)	12 (13.2)	14 (11.9)	0.304
Migration, n (%)	7 (7.7)	20 (16.9)	0.045
Tissue growth, n (%)	9 (9.9)	24 (20.3)	0.046

SD standard deviation

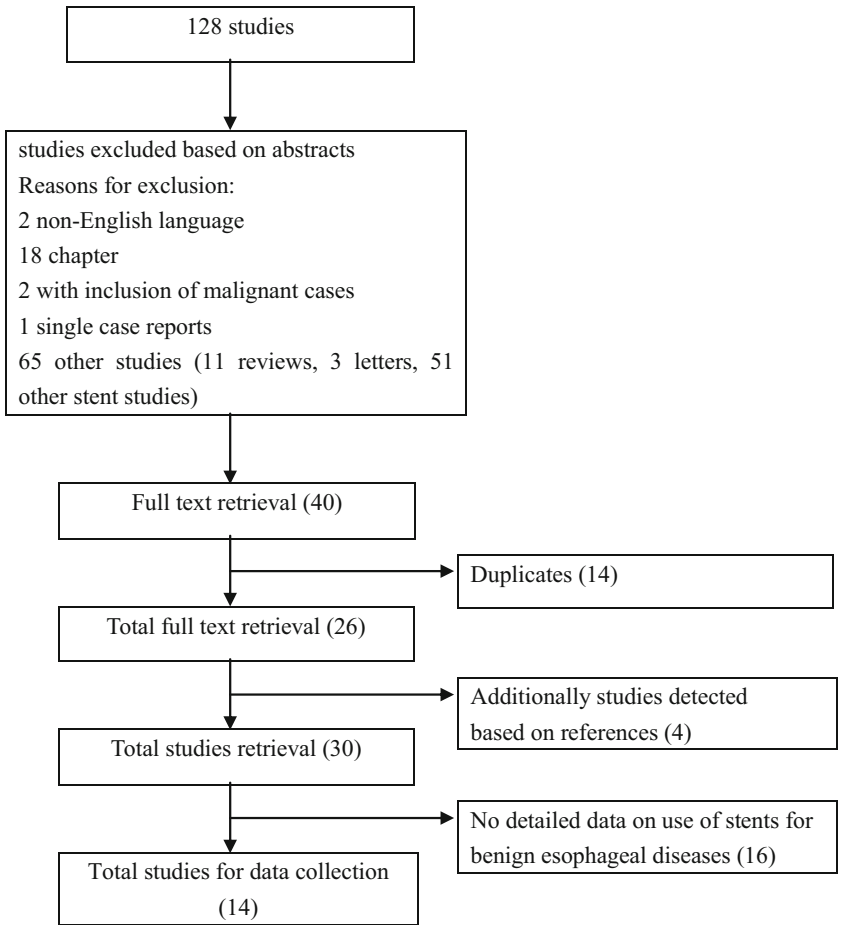

Fig. 1 Flowchart of search history on stents for benign esophageal diseases

Discussion

In our studies, most of the patients (50.7 %, excluding the missing) are treated with endoscopic dilation using bougies or balloons before stent placement. The immediate success rate of dilation in relieving dysphagia is 80 to 90 %, with only a few complications [19–23]. However, recurrent symptoms after dilation within the first year frequently occurred. And surgery can provide definitive treatment but has been associated with considerable mortality and morbidity, including the development of new anastomotic strictures [9, 15, 19, 24, 25]. So, unsuccessful management of benign esophageal stricture by serial endoscopic dilatation or surgery and the management of these refractory strictures have been considered challenging [9, 26, 27].

As a result, the use of temporary stent for the treatment of benign esophageal disease has advanced immensely over the past decade. Temporary placement of self-expandable stents is now used in a variety of benign conditions, including postoperative anastomotic leak, refractory strictures due to peptic ulcers or radiation, and tracheoesophageal fistula [28]. In most benign esophageal conditions, covered SEMS is recommended to use as removal of these stents is easier due to the absence of reactive tissue ingrowth through the uncovered stent mesh [29, 30]. However, metal stents have some deficiencies such as migration, hyperplastic tissue, etc. As a consequence, BD stents have been developed to overcome these problems and have a good clinical effect.

We did a study compared BD stents with SEMS placement in patients with benign esophageal disease of 323 treated patients on various items. Regarding to the clinical success of SEMS and BD stents, the results of our study are clearly shown in Table 4. Clinical success of stent placement was achieved in 47.7 % of reported patients with no significant differences between BD stents and SEMS. The technical success rate of stent placement was 95.4 %, and there was similarly no significant difference. The mortality is 3.4 % in all patients, and the most of the deaths were from BD stents group. However, the death of most patients was irrelevant to BD stents insertion. Only one patient died of the stent. There is no true evidence comparing stent placement and other kinds of treatments. Nonrandomized trial and limited number of patients for such a trial are the cause of difficulties.

The mean time of stent placement for treatment was 12 and 7 weeks, respectively. The mean time of BD stents placement is longer than SEMS; therefore, the duration of BD stents on esophageal lesions is enough. Not only that, the main advantage

over SEMS is that endoscopic removal is not needed. BD stents can be metabolized by the body within about 12 weeks.

Stent migration occurred in 29.4 % of patients and was most often occurred with SEMS, compared with BD stents. This result is consistent with subgroup analysis. That is explained by the known reduced anchoring capacity of SEMS compared with BD stents. Furthermore, as the far majority of these patients have no obstructive lesion keeping the stent in place, stent migration is the main factor for re-intervention with SEMS. Re-intervention for incomplete sealing, a procedure-related or stent-related complication, was performed more with SEMS than with BD stents. However, by the subgroup analysis for BRES, there was no clinical statistical significance for re-intervention between BD stents with SEMS. Two types of stents are not guaranteed to solve the problem once. Most patients required multiple interventions.

Tissue in- and/or overgrowth was higher with SEMS than with BD stents, and the same result to subgroup analysis for BRES. Tissue embedment after stent placement renders removal of the stents very difficult, and this benign tissue reaction, which is caused by a local fibrotic reaction and/or the proliferation of granulation tissue, particularly occurs at the uncovered part of SEMS. The majority of SEMS this paper involved is FCSEMS. It has been shown that FCSEMS may be able to overcome the problems of partially or completely uncovered SEMS. The FCSEMS that is applied along its whole length prevents tissue from growing into the stent meshes. However, BD stents are made of a covered mesh and manufactured from polymeric materials including polylactic acid, polyglycolic acid, polycaprolactone, and copolymers or composites of these materials. And recent clinical data are available for the Ella BD stent (Ella-SX, s.r.o., Hradec Kralove, Czech Republic), which is made of polydioxanone. Hence, these stents do not need manual removal. The stents are covered, and tissue in-growth, if it occurs, can anchor the stents.

Some limitations of our study should be taken into account before concluding that a particular stent type is favorable in patients with benign esophageal disease. First, no randomized trials have been conducted. The patient groups are heterogeneous. Our study had a relatively low number of patients per group, which limited the study's statistical strength. Another potential weakness is the different time to follow-up for the two groups. The BD stent group has a longer follow-up period, which could have influenced the final outcome because, theoretically, the longer the follow-up period is, the higher the probability of dysphagia recurrence. Some studies show that the benefits of temporary stent decreased rapidly with time for non-responders [6, 7, 12, 17, 23].

In conclusion, this review demonstrates that stent placement in patients are effective and safe for benign esophageal disease. It can decrease the burden of repeated endoscopic dilation. Most of the benefits (such as clinical success, technical success and mortality) between BD stents and SEMS were not found to be significantly different; however, a clear advantage of BD stents is that there are fewer complications after completion of the treatment. And BD stents can be metabolized; endoscopic removal is not needed. But the ideal treatment strategy in these patients still needs to be defined, and further randomized trials with large number of patients are needed to compare different stent types.

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Conflict of Interest The authors declare that they have no competing interest.

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