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Management of occluded metal stents in malignant biliary obstruction: similar outcomes with second metal stents compared to plastic stents

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Abstract

Background—Covered or uncovered self expandable metallic stents (SEMS) placed in patients with malignant biliary obstruction can occlude in 19–40%, but optimal management is unclear.

Aim—We sought to summarize current evidence regarding management of occluded SEMS in patients with malignant biliary obstruction.

Methods—Two investigators independently searched Pubmed, Embase, and Web of Science using pre-defined search criteria, and reviewed bibliographies of included studies. Data were independently abstracted by two investigators, and analyzed using RevMan. We compared strategies of second SEMS versus plastic stents with respect to the following outcomes: rate of second stent re-occlusion, duration of second stent patency, and survival.

Results—Ten retrospective studies met inclusion criteria for the systematic review. Management options described were placement of an uncovered SEMS (n=125), covered SEMS (n=106), plastic stent (n=135), percutaneous biliary drain (n=7), mechanical cleaning (n=18), or microwave coagulation (n=7). Relative risk of re-occlusion was not significantly different in patients with second SEMS compared to plastic stents (RR 1.24, 95% CI 0.92, 1.67, I²= 0, p 0.16). Duration of second stent patency was not significantly different between patients who received second SEMS versus plastic stents (weighted mean difference 0.46, 95% CI –0.30, 1.23, I²=83%). Survival was not significantly different among patients who received plastic stents versus SEMS (weighted mean difference –1.13, 95% CI –2.33, 0.07, I² 86%, p 0.07).

Conclusions—Among patients with malignant biliary obstruction and occluded SEMS, available evidence suggests a strategy of placing a plastic stent may be as effective as second SEMS. Limitations of these findings were that all studies were retrospective and heterogeneity between studies was detected for two of the outcomes.

Background

Initial endoscopic placement of a self-expandable metallic stent (SEMS) is associated with longer patency and lower risk of cholangitis compared to conventional polyethylene stents in patients with malignant biliary obstruction [1–5]. Although SEMS cost more than plastic stents, initial use of a SEMS is a cost-effective approach for patients expected to live longer than 3 months because fewer subsequent endoscopic retrograde cholangiopancreatography (ERCP) procedures are required [4, 5].

Nonetheless, SEMS is associated with an occlusion rate of 19%–40% which has remained largely unchanged in spite of modifications in stent composition and the addition of a plastic coating [6–11]. Occlusion is attributed to epithelial hyperplasia, tumor in-growth and overgrowth, dislocation, debris formation, and clot accumulation [1–3, 12]. Consensus is lacking for the optimal management of occluded SEMS in patients with malignant biliary obstruction.

We conducted a systematic review and meta-analysis to assess the effectiveness of various management approaches. We hypothesized that although second SEMS would be associated with longer patency and lower re-occlusion rate than plastic stents, the patency of second SEMS would be shorter than that reported for the initial SEMS due to reduced life expectancy.

Methods

Search strategy and study selection

Two study investigators (TS, SD) independently searched Pubmed, Embase, and Web of Science in March 2011 for studies evaluating management of occluded SEMS in patients with malignant biliary occlusion. Search criteria were developed *a priori* in consultation with a health sciences librarian at Duke University Medical Center (Table 1). Full text of potentially relevant articles were obtained and evaluated for exclusion criteria (Table 2). The bibliographies of all relevant articles were hand searched for relevant studies that were not identified on the initial search. Disagreements in study selection were resolved by consensus, or discussion with a third investigator who was a senior advanced endoscopist (MH).

Data abstraction

Data were independently abstracted by two study investigators (TS, HD) on a Microsoft Excel spreadsheet (XP, Professional edition; Microsoft, Redmond, WA), and reviewed for accuracy by a third investigator (SD). Abstracted outcomes were duration of stent patency (continuous), occurrence of stent re-occlusion (dichotomous outcome), and survival (continuous). We abstracted means and standard deviations of continuous variables when these were available, and calculated these values from medians and ranges (obtained either from the text or Kaplan-Meier curves) when the mean and standard deviation was not reported [11]. We contacted authors to obtain additional information when data were missing for our study outcomes.

Statistical analysis

Studies that reported management of occluded SEMS with both SEMS and plastic stents were included in the meta-analysis in order to compare pooled outcomes between strategies of second SEMS versus plastic stent placement. All statistical analyses were performed using Review Manager Version 5 (RevMan for Windows 2008, the Nordic Cochrane Center, Copenhagen, Denmark). Outcomes were assessed using a random effects model to give a more conservative estimate of treatment effect that accounted for heterogeneity between studies [10]. Duration of second stent patency and survival using a strategy of second metal stent versus plastic stent were compared using weighted mean differences and 95% confidence intervals. Rates of re-occlusion with second metal stents versus plastic stents were compared using risk ratios and 95% confidence intervals. All of the above outcomes were represented graphically using Forest plots.

Heterogeneity across studies for each of these outcomes was assessed using the I^2 statistic, which ranges from 0 to 100% (0% represents no heterogeneity and larger values indicate

increasing heterogeneity). A value of $I^2 < 50\%$, accompanied by a P-value of > 0.10 for the chi-square test was considered to represent low levels of heterogeneity. We assessed for publication bias graphically by visual inspection of funnel plot symmetry.

Results

The initial search yielded 1416 citations in Pubmed, 710 citations in Embase, and 475 citations in Web of Science (figure 1). Of the 24 citations initially identified as potentially relevant on Pubmed, nine met inclusion criteria [9, 13–20]. One additional article was included after performing bibliography search of the nine included studies [21]. All of the 10 potential citations in Embase and 13 potential citations in Web of Science were excluded, since they were either duplicates or abstracts. All of the studies were retrospective (Table 3). The Pubmed search was updated on a monthly basis until February 2012 and no new publications meeting inclusion criteria were found.

The 10 included studies represented 392 patients with malignant bile duct, hilum, or hepatic duct obstruction and an occluded SEMS. Sample size in individual studies ranged from 13 to 77 patients (Table 4). In one of the studies, only patients with distal common bile duct obstruction were included [14]. In another study, patients with hilar obstruction were not included [15]. Pancreatic cancer was the most common cause of biliary obstruction in 9 of the 10 studies ($n=225$). Cholangiocarcinoma and metastatic disease were the second and third most frequently listed malignancies respectively.

The initial occluded stent was an uncovered metal stent in 271 patients and a covered metal stent in 44 patients. Nine of the 10 studies commented on cause of initial SEMS occlusion. The most frequently reported cause of initial SEMS occlusion was tumor ingrowth ($n=187$) followed by sludge or debris ($n=54$) and tumor overgrowth ($n=46$). A combination of tumor ingrowth and debris was responsible for initial SEMS occlusion in 25 patients [20]. A combination of tumor ingrowth and overgrowth was reported in 9 patients from one study [17]. The type of occluded SEMS was not specified for 77 patients from 2 studies [15, 19]. The initial stent was placed endoscopically in 224 patients and percutaneously in 25 patients. The route of stent placement was not specified for the remaining 143 patients from 4 studies [13, 15, 20, 21]. In one study, there were 38 patients with 44 occlusions and outcomes were reported for each occlusion [17]. Initial SEMS diameter was not reported in all studies, but when this information was included, a 10 French diameter stent was most frequently used.

Management options described for occluded SEMS were placement of another uncovered SEMS ($n=125$), covered SEMS ($n=106$), plastic stent ($n=135$), percutaneous biliary drain ($n=7$), mechanical cleaning ($n=18$), or microwave coagulation ($n=7$). The second stent was placed endoscopically in 294 patients and percutaneously in 8 patients. Route of stent placement was not specified for 90 patients from 2 studies [13, 21]. In one of the studies, 21 occluded SEMS and 35 plastic stents were managed with placement of a covered Wallstent [15]. Outcomes among patients with initial plastic and metal stents in this study were pooled, so patency and survival with a covered Wallstent in patients with occluded SEMS alone could not be assessed [15]. None of the studies reported whether or not plastic stents were electively replaced every 2–6 months to pre-empt stent occlusion, as is common practice at many centers.

Outcome: second stent re-occlusion

The proportion of patients with a second stent occlusion was reported in 7 of the 8 studies that described both second SEMS and plastic stents for management of SEMS occlusion. In the second SEMS group, 65/190 stents occluded. In the plastic stent group, 56/124 stents

occluded. Relative risk of re-occlusion was not significantly different in patients with second SEMS compared to plastic stents (RR 1.24, 95% CI 0.92, 1.67, $I^2=0$, p 0.16) (Figure 2). Funnel plot inspection was not suggestive of significant publication bias (Figure 3).

Four studies utilized both covered and uncovered SEMS as the second stent [13, 16, 18, 19]. Three of these 4 studies reported proportion of patients with re-occluded covered and uncovered SEMS [13, 16, 18]. When these three studies were pooled, a strategy of using a covered SEMS compared to an uncovered SEMS as the second stent was not associated with a significantly different re-occlusion rate (RR 1.43, 95% CI 0.58, 3.55, I^2 57%, p 0.44).

Outcome: duration of second stent patency

Median duration of second stent patency ranged from 54 to 192 days for patients managed with uncovered SEMS, 138–214 days for covered SEMS, 60–106 days for plastic stents, and 21–112 days for mechanical cleaning (Table 5). Mean and standard deviation for duration of second stent patency were reported or calculable in 5 of the 8 studies that described both second SEMS and second plastic stents for management of SEMS occlusion. When the results of these studies were pooled, duration of second stent patency was not significantly different between patients who received second SEMS ($n=157$) versus plastic stent ($n=93$) (weighted mean difference 0.46, 95% CI -0.30 , 1.23 , $I^2=83\%$, p 0.23) (Figure 4). Funnel plot inspection was not suggestive of significant publication bias (Figure 5). We did not compare duration of stent patency between covered and uncovered SEMS because means and standard deviations were calculable for only 2 studies that utilized both stent types.

Outcome: survival

Median survival ranged from 70–389 days for uncovered SEMS, 198–440 days for covered SEMS, 90–296 days for plastic stents, and 34–210 days for mechanical cleaning. Mean and standard deviation for survival were reported or calculable in only 2 of the 8 studies that described both second SEMS and second plastic stents for management of SEMS occlusion [13, 14]. When the results of these 2 studies were pooled, survival was not significantly different among patients who received plastic stents versus second metal SEMS (weighted mean difference -1.13 , 95% CI -2.33 , 0.07 , I^2 86%, p 0.07).

Costs and cost-effectiveness

Although our literature search did not identify any formal cost-effectiveness analyses, three of the included studies attempted to address the cost of various strategies for managing SEMS occlusion from the perspective of endoscopic utilization. One study calculated a cost benefit favoring a strategy of plastic stents when compared to uncovered SEMS or mechanical cleaning [14]. Another study concluded that the incremental cost-effectiveness of plastic stents and second SEMS was superior to a strategy of mechanical cleaning. This study also concluded that uncovered SEMS were more cost effective than plastic stents when the cost of an ERCP exceeded \$1967 [16]. The third study concluded that plastic stents were the most cost-effective option for management of occluded SEMS [17].

Discussion

In patients with malignant biliary obstruction, robust data suggest that the higher cost of an initial SEMS may be mitigated by the reduced need for repeated ERCP [4, 5]. This literature is not infrequently extrapolated in clinical practice as a rationale to place another SEMS in patients with occluded SEMS. Unfortunately, the natural history of patients who develop SEMS occlusion is to have a shorter survival compared to when the stent was initially placed for malignant jaundice. Indeed, in this systematic review median survival ranged from merely 70 days to 440 days. Thus, the likelihood of surviving long enough to develop

second stent occlusion is significantly lower than with initial stent placement. Our meta-analyses did not reveal significant differences in re-occlusion rates or stent patency between strategies of second SEMS compared to plastic stents. While this study did not directly assess cost-effectiveness, these results suggest that management of occluded SEMS with a plastic stent may be less expensive and equivalently effective.

On the other hand, the range of survival when reported (three studies) was wide, with maximum survival > 2 years in one study and >8 years in another. These findings highlight the need to account for a patient's performance status when making decisions regarding second metal versus plastic stent placement.

Exclusion of non-English language studies can potentially bias the estimate of treatment effect. Only one non-English study was identified during the initial search. Inclusion of this article is unlikely to have changed overall study results because initial stent occlusion (plastic and metal) occurred in only 12 patients. Furthermore, the English abstract suggests that this article would have been excluded because the authors describe management of both benign and malignant strictures using initial plastic stents and SEMS [22].

A limitation of our findings is that all studies were observational in design, and therefore patient assignment to different interventions is subject to selection bias. Indeed, we noted that the percentage of patients who received a second plastic stent in each study included in the meta-analysis varied from 14% to 84%. An endoscopist's decision to place a plastic, uncovered metal, or covered metal stent is likely to be influenced by the location of the occlusion as well as perception of the patient's performance status. Since a patient with poor perceived performance status is probably more likely to receive a plastic stent, we would expect selection bias to skew re-occlusion rate and patency in favor of second SEMS. However, in our meta-analyses re-occlusion rate and patency were not significantly improved with a strategy of second SEMS. Finally, our results must be interpreted in context of the significant heterogeneity observed between studies for one of the outcomes.

To our knowledge, this is the first study to systematically review the literature regarding optimal management of SEMS occlusion in patients with malignant biliary obstruction. In the absence of randomized controlled trials, our study summarizes the best available information to address this common and difficult clinical scenario. Strengths of the study include the systematic search criteria, independent literature search and abstraction by separate investigators for accuracy, and the application of well-defined statistical methodology to pool results of different studies.

In summary, management of occluded SEMS in patients with malignant biliary obstruction using a strategy of second SEMS does not appear to reduce re-occlusion rates or improve duration of second stent patency when compared to a strategy of plastic stent placement. Prospective studies that account for location of obstruction and performance status in decision making are necessary to more definitively guide management.

Acknowledgments

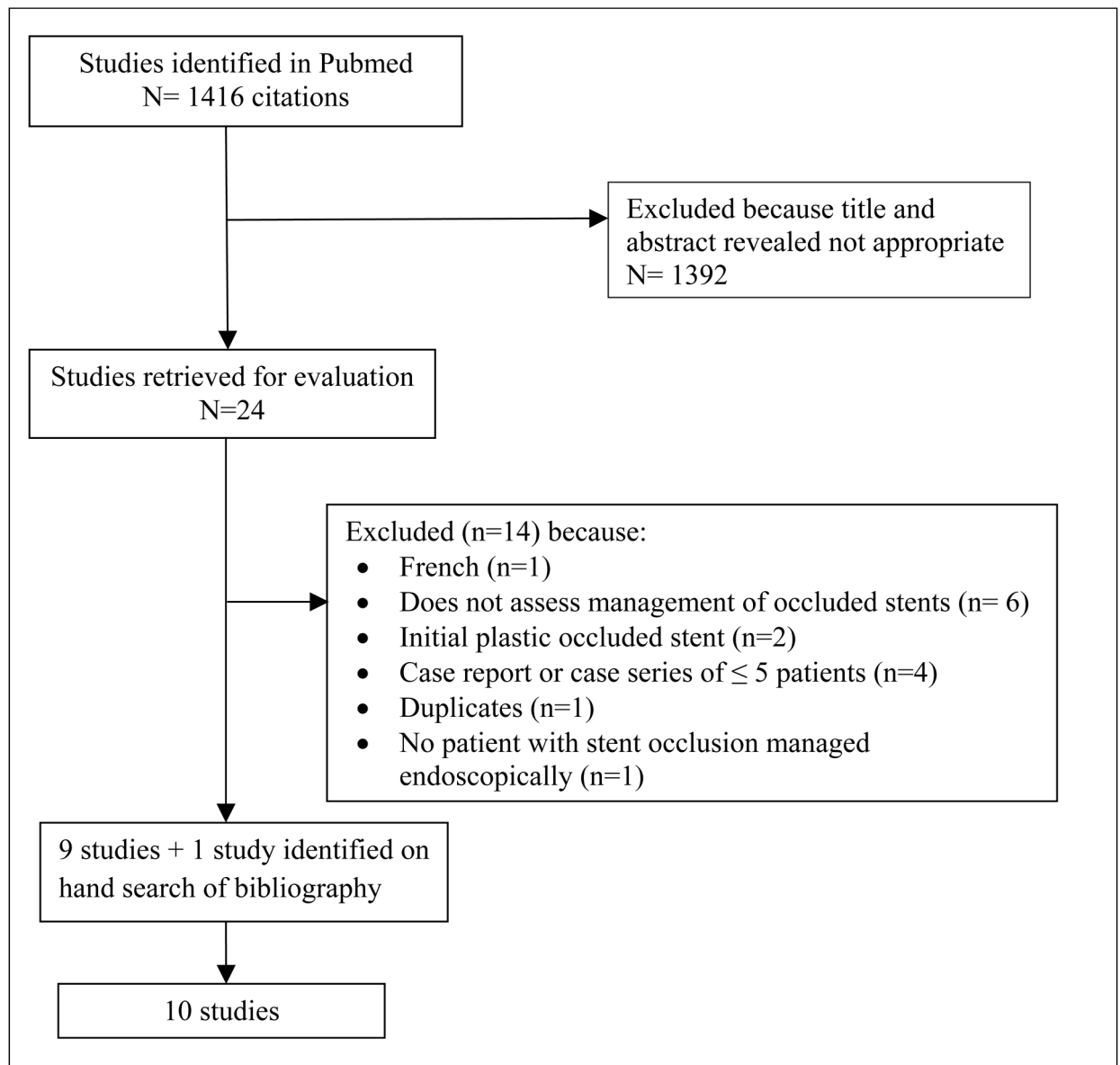
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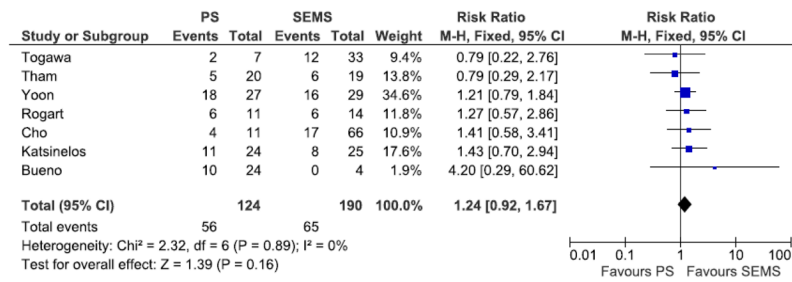
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**Figure 1.**

Flow diagram of studies identified in the systematic review

Search revealed 710 citations in Embase, and 475 citations in Web of Science. All of the 10 potential citations in Embase and 13 potential citations in Web of Science were excluded, since they were either duplicates or meeting abstracts.

**Figure 2.**

Forest plot comparing proportion of patients with re-occluded plastic stents (PS) versus self expandable metal stents (SEMS)

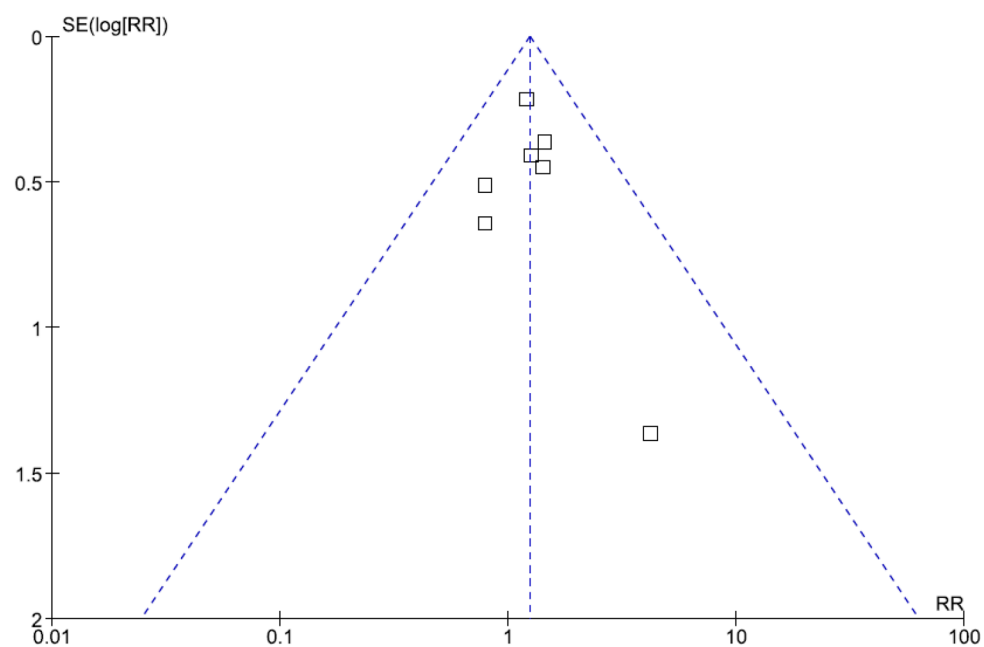


Figure 3.
Funnel plot of studies assessing proportion of patients with reoccluded plastic stents (PS) versus self expandable metal stents (SEMS)

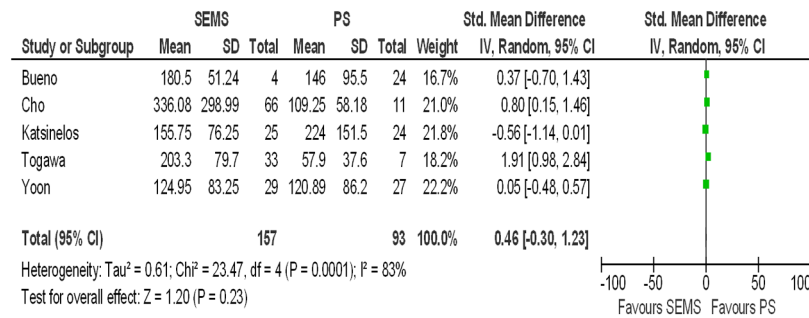


Figure 4.
 Forest plot comparing patency in days of second self-expandable metal stents (SEMS) versus plastic stents (PS) placed in patients with initial SEMS occlusion

Table 1

Search strategy used for Pubmed, Embase, and Web of Science

Pubmed	((endoprosthese* OR endoprosthesis* OR stent OR stents OR stenting) AND ((malignant biliary obstruction OR ("Digestive System Neoplasms"[Mesh] OR malignant OR malignancy) AND (Cholestasis OR biliary obstruction))) OR (obstructive jaundice) OR (biliary obstruct*) OR (biliary obstruction))) NOT (Editorial[ptyp] OR Letter[ptyp] OR Case Reports[ptyp] OR Comment[ptyp])
Embase	'bile duct obstruction'/exp OR 'cholestasis'/exp OR biliary AND obstruction OR 'obstructive jaundice'/exp AND (malignant OR malignancy OR 'digestive system tumor'/exp) AND ('stent'/exp OR stent OR stents OR stenting OR endoprosthesis OR endoprostheses) AND [embase]/lim NOT [medline]/lim
Web of science	cholestasis OR biliary obstruct* OR obstructive jaundice in Title AND endoprosthese OR endoprosthesis OR stent* in Title

Table 2

Exclusion criteria

1	Non-English language studies
2	Animal and pediatric studies
3	Case reports and case series (5 patients)
4	Letters, editorials, and abstracts
5	Studies on benign biliary strictures
6	Studies that were not directed towards management of biliary SEMS occlusion
7	Endoscopic management of occluded stent not utilized for any of the patients in study

Table 3

Characteristics of included studies

Author	Journal Year	Country	Duration of follow up	Definition: duration of stent patency
Katsinelos	World Journal of Gastroenterology 2011	Greece	All patients followed until death	Days to repeat intervention or death
Yoon	World Journal of Gastroenterology 2010	South Korea	All patients followed until death	Days to re-occlusion or death
Cho	Surgical Endoscopy 2011	South Korea	Re-occlusion or death	Days to re-occlusion or death
Ridtidid	Surgical Endoscopy 2010	Thailand	Repeat intervention, death, or February 2009	Days to repeat intervention, death, or February 2009
Ornellas	Gastrointestinal Endoscopy 2009	USA	Repeat intervention, death, or February 2006	
Rogart	Gastrointestinal Endoscopy 2008	USA	Until repeat intervention	Days to repeat intervention
Togawa	Journal of Clinical Gastroenterology 2008	Japan	Re-occlusion or death	Death without obstruction censored at time of patency analysis
Tham	Gut 1998	USA	Re-occlusion or death	Days to re-occlusion or death
Bueno	Gastrointestinal Endoscopy 2003	USA	Re-occlusion, death, repeat intervention, or March 2002	Days to re-occlusion, repeat intervention, death, or March 2002
Maetani	Hepato-gastroenterology 2001	Japan	Re-occlusion or death	Day to re-occlusion or death

All included studies were retrospective chart reviews

Table 4

Types of stents used in various studies

Study	Sample size	Type of initial occluded stent	Initial stent route	Management of occluded stent	2 nd stent route
Katsinelos	54	54 USEMS (Hanaro, Flexus, stainless steel Wallstent)	54 ERCP	25 USEMS 24 PS (10 Fr) 5 Cleaning	54 ERCP
Yoon	56	56 SEMS	46 ERCP 10 Perc.	19 USEMS (Wallstents or Niti-S stents) 10 CSEMS (Wallstents) 27 PS (10 Fr Amsterdam or Colton-Leung)	56 ERCP
Cho	77	47 USEMS 30 CSEMS	Not specified	26 USEMS 40 CSEMS 11 PS	Not specified
Ridtidid	32	22 USEMS 10 CSEMS	Not specified	14 USEMS 11 PS 7 PTBD	25 ERCP 7 Perc.
Ornellas	21	21 SEMS 35 Plastic stents	Not specified	21 CSEMS (Wallstent)	21 ERCP
Rogart	27	23 USEMS (Wallstent) 4 CSEMS (wallstent)	27 ERCP	5 USEMS (Wallstent) 9 CSEMS (Wallstent) 11 PS (10 Fr straight or 10 Fr double pigtail) 2 Cleaning	27 ERCP
Togawa	40	40 USEMS (Wallstents, Diamond stents, and SMART stents)	40 ERCP	7 USEMS (Wallstent, Diamond stent, SMART stent) 26 CSEMS (Wallstent, Diamond stent) 7 PS (Flexima, Tannenbaum)	40 ERCP
Tham	38	38 patients with 44 Wallstent occlusions	37 ERCP 1 Perc.*	19 USEMS (wallstent) 20 PS 5 Cleaning	Perc. in 1 patient
Bueno	34	34 USEMS (Wallstent)	21 ERCP 14 Perc.	4 USEMS (wallstent) 24 PS (10 Fr Amsterdam) 6 Cleaning	34 ERCP**
Maetani	13	13 USEMS (Wallstent, Accuflex, and Symphony)	ERCP or Perc.	6 USEMS (Wallstent) 7 Microwave coagulation	ERCP or Perc.

ERCP - Endoscopic retrograde cholangiopancreatography; Perc. - Percutaneous; SEMS = self expandable metallic stent; CSEM - covered SEM; USEM - uncovered SEM; PS - Plastic stent; PTBD - Percutaneous transhepatic biliary drainage

* Data not available for 1 patient

** 1/35 patients had percutaneously inserted stent and was excluded from analysis by authors

Table 5

Median patency and survival

Study	Median patency in days	Range patency in days	Median survival in days	Range of survival in days
Katsinelos				
USEMS	133	26–331	177	60–870
PS	106	39–645	106	40–645
Cleaning	112		210	39–390
Yoon				
USEMS	60	11–285	200	
CSEMS	186	19–268	200	
PS	66	3–348	133	
Cho				
USEMS	109	8–628	243	24–1457
CSEMS	138	13–1374	440	90–3088
PS	88	32–229	296	168–590
Riddidid				
USEMS	100		230	
PS	60			
PTBD	75		130	
Ornellas				
CSEMS*	348		178	
Rogart				
USEMS	54		389	
CSEMS	214		227	
PS	66		188	
Togawa				
USEMS	61	6–437	239	
CSEMS	220	19–198	198	
PS	45	13–130	90	
Tham				
USEMS	75		70	
PS	90		98	
Bueno				
USEMS	192	81–257		
PS	90	11–393		
Cleaning	21			
Maetani				
USEMS	104	32–104	78	45–110

CSEM – covered SEM; USEM – uncovered SEM; PS – Plastic stent

Missing fields indicate information is not reported in text or graphs, and not provided by authors when emailed by study investigators.

* Outcome reported includes patients with initial occlu