

## Long-Term Outcome of Self Expandable Metal Stents for Biliary Obstruction in Chronic Pancreatitis

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### ABSTRACT

**Context** Insertion of a self-expandable metal stent is still controversial for treatment of benign common bile duct stenosis but can be a valuable alternative to surgical treatment. **Objective** Aim of our study was to analyze the efficacy of covered and uncovered self-expandable metal stent in patients with chronic pancreatitis and common bile duct stenosis. **Material and methods** Twenty patients with common bile duct stenosis due to alcoholic chronic pancreatitis were retrospective analyzed. All patients had advanced chronic pancreatitis, presenting with calcifications in pancreatic head. Uncovered self-expandable metal stent (*u*SEMS) were used in 11 patients (3 females, 8 males) while in 9 patients (3 females, 6 males) partially covered self-expandable metal stent (*c*SEMS) were inserted. All patients treated with self-expandable metal stent had contraindications for surgery. **Results** Overall mean follow up time was 155 weeks: 206 (52-412) weeks in *u*SEMS, and 93 (25-233) weeks in *c*SEMS, respectively. Stent patency was in mean 118 weeks: 159 (44-412) weeks in *u*SEMS and 67 (25-150) weeks in *c*SEMS ( $P=0.019$ ). In the *u*SEMS group, reintervention was necessary in 5 patients (45%) due to stent obstruction, whereas in the *c*SEMS group 4 patients (44%) needed reintervention (2 obstructions, 2 migration). Stent migration is an early complication, compared to obstruction ( $P<0.05$ ), and in *c*SEMS obstruction occurred significantly earlier compared to *u*SEMS ( $P<0.05$ ). **Conclusion** Patency of *u*SEMS was significantly longer compared to partially *c*SEMS. Available self-expandable metal stent, unfortunately, do not meet the demands on successful treatment of benign common bile duct stenosis.

### INTRODUCTION

Chronic pancreatitis is a disease most commonly caused by chronic alcohol abuse and characterized by inflammation and destruction of pancreatic acini and their replacement by fibrotic tissue [1]. A stenosis of the distal (intrapancreatic) common bile duct due to fibrosis and/or inflammation occurs in 10-30% of patients [2, 3, 4], leading to cholestasis and subsequent jaundice. Drainage is recommended to prevent cholangitis and the development of secondary biliary cirrhosis.

Gold standard in the treatment of common bile duct obstruction related to chronic pancreatitis are surgical interventions, namely resection of pancreatic head or

biliodigestive anastomosis [5, 6]. Surgery is related to a considerable risk of morbidity and mortality. Rate of surgical reintervention rates after pancreatic surgery in chronic pancreatitis range from around 5% to over 50%, depending on follow up time and definition of indication for reintervention [7, 8]. A subgroup of patients is not eligible for pancreatic surgery, most frequently because of elevated risk due to portal hypertension or comorbidity.

Endoscopic interventions are less invasive techniques for achieving drainage of common bile duct obstruction in patients with obstructive cholestasis due to chronic pancreatitis. Plastic stent insertion has a lower peri-interventional morbidity compared to surgery [9]. It is inexpensive, reversible and repeatable if necessary, making it a desirable first therapeutic approach for patients with common bile duct obstruction [10]. Limiting factors are either stent dysfunction and clogging due to bacterial colonization or stent dislocation [4, 11, 12]. Plastic stents have to be exchanged, usually three monthly, to prevent stent clogging [13]. Taking into consideration the relatively long potential life expectancy of patients suffering from chronic pancreatitis, long-term plastic stenting

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**Abbreviation** *c*SEMS: covered self-expandable metal stent; *u*SEMS: uncovered self-expandable metal stent

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does not seem a suitable therapeutic concept, as it leads to a considerable cumulative intervention risk of endoscopic retrograde cholangiopancreatography, high costs, and patient stress [14].

It has also been shown that in most patients plastic stenting does not lead to a complete regression of common bile duct stenosis. Because of long-term success rates of around 30% plastic stenting is not a promising concept for definite treatment of common bile duct stenosis in a substantial number of patients [4, 5, 15, 16, 17]. Although insertion of multiple stents has been shown to improve results, recurrence of symptomatic common bile duct stenosis has to be expected in most cases [10, 18, 19]. Acute pancreatitis was identified as positive predictive factor, whereas calcifications in pancreatic head were identified as negative predictive factor for successful plastic stent treatment of common bile duct obstruction [15, 17].

Self expandable metal stents may be an alternative of plastic stents for patients not eligible for surgery. They have been identified as a treatment option for malignant common bile duct obstruction [20]. Advantages of self-expandable metal stent are larger diameters, longer stent patency, no need for elective removal and rare spontaneous stent migration. In patients with malignant diseases average stent patency has shown to range from 130 to 400 days, mainly correlating with patients survival [21, 22, 23, 24]. In most cases a definitive resolution of jaundice can be achieved by self-expandable metal stent placement. Compared to uncovered self-expandable metal stent (*uSEMS*), covered self-expandable metal stent (*cSEMS*) are less frequently used in malignant biliary obstruction because of more frequent complications (stent migration, pancreatitis or cholecystitis) at similar or reduced patency rates compared to *uSEMS* [22, 23, 25]. Self-expandable metal stent dislocation can lead to severe complications including stent buckling, rupture and impaction with consecutive ulceration and/or perforation of the duodenal wall or intestinal perforations [25, 26].

To avoid complications three- to six-month intervals for *cSEMS* exchange have been tested with satisfying data [26, 27].

However, the use of self-expandable metal stent in benign causes of common bile duct stenosis is still controversial.

The aim of our study is to evaluate the long-term outcome of patients with common bile duct obstruction due to chronic pancreatitis treated with self-expandable metal stent. Main outcome data analyzed were stent patency, complications, and time to complication in a long-term follow-up.

## METHODS

Patient data were retrospectively collected using full text research in the electronic databases of Otto-von-Guericke-University, in Magdeburg, and DRK-Kliniken Berlin I Köpenick, Germany, during the

period from 1999 to 2009. All patients who had undergone definitive self-expandable metal stent implantation because of common bile duct stenosis due to alcoholic chronic pancreatitis were included. The selection of covered or uncovered stents was made due to availability of the stents (in the first 5 years of the study period covered stents were not or not widely available). In cases with gallbladder in situ uncovered stents were the first choice. All patients had undergone plastic stent treatment before (1-17 times), and were rejected from surgery by an interdisciplinary board of surgeons, gastroenterologists and anesthesiologists because of at least one contraindication. Most common and strongest factor, qualifying patients unfit for surgery was portal hypertension due to portal vein thrombosis. Additionally, comorbidity and/or refusing surgery qualified patients for self-expandable metal stent-treatment. Uncovered stents of different length from two manufacturers were used: Zilver-Stent® (Cook Medical Deutschland, Mönchengladbach, Germany) and Hanaro-Stent® (MTW Endoskopie, Wesel, Germany); covered stents (Nitinol-TTS) of different length were from Micro-Tech Europe, Düsseldorf, Germany. In all patients stents were placed endoscopically.

Patient data collected were gender, age, presence of calcifications in the pancreatic head, pancreatic exocrine and endocrine function, number and type of biliary drainage interventions before and after self-expandable metal stent placement, method of stent implantation, stent patency and complications. Reintervention was defined as any manipulation on stent or common bile duct stenosis due to clinical or laboratory signs of cholestasis.

## ETHICS

The study was performed with respect to the corresponding sections of the "World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects" adopted by the 18<sup>th</sup> WMA General Assembly, Helsinki, Finland, June 1964 and amended by the 59<sup>th</sup> WMA General Assembly, Seoul, South Korea, October 2008. Approval of an IRB was not obtained, due the fact that in a retrospective study already realized medical treatments were analyzed. All patients gave written informed consent prior to endoscopic interventions and prior to data analyzing.

## STATISTICS

Data were collected in a database using Excel 2002 (Microsoft Corporation, Redmond, WA, USA). Descriptive statistics were performed with numerical data presented as means and ranges, and medians if not indicated otherwise. Estimated stent patency was shown as Kaplan-Meier plot. Times were compared by mean of the log-rank test. All calculations were performed using SPSS (Version 14.0 for Windows; SPSS Inc., Chigaco, IL, USA).

**Table 1.** Patient data.

Patient ID	Age (years)	Interventions before SEMS	Number of reinterventions	Portal hypertension	Cambridge classification	Diabetes mellitus	Exocrine insufficiency
<b>Uncovered self-expandable metal stent (<i>u</i>SEMS)</b>							
#1	61	2	6	No	Grade III	No	No
#2	54	3	9	Yes	Grade III	Yes	Yes
#3	32	5	0	No	Grade III	Yes	Yes
#4	69	2	0	No	Grade III	Yes	Yes
#5	41	2	1	Yes	Grade III	Yes	Yes
#6	61	6	0	No	Grade III	Yes	Yes
#7	54	3	0	Yes	Grade III	Yes	Yes
#8	45	4	0	Yes	Grade III	Yes	Yes
#9	38	3	3	Yes	Grade III	No	Yes
#10	52	6	0	Yes	Grade III	Yes	Yes
#11	31	2	3	Yes	Grade III	No	Yes
<b>Total</b>	<b>48.9</b> (31-69) <sup>a</sup>	<b>3.5</b> (2-6) <sup>a</sup>	<b>4.4</b> (1-9) <sup>ab</sup>	<b>7</b> (63.6%)	<b>Grade III</b> <b>11 (100%)</b>	<b>8</b> (72.7%)	<b>10</b> (90.9%)
<b>Covered self-expandable metal stent (<i>c</i>SEMS)</b>							
#1	55	8	0	Yes	Grade III	No	Yes
#2	50	4	5	No	Grade III	Yes	Yes
#3	36	1	2	Yes	Grade III	Yes	Yes
#4	62	17	0	Yes	Grade III	Yes	Yes
#5	43	1	1	No	Grade III	No	Yes
#6	44	6	0	Yes	Grade III	Yes	Yes
#7	56	2	0	Yes	Grade III	No	Yes
#8	39	1	0	Yes	Grade III	No	Yes
#9	50	2	1	Yes	Grade III	No	Yes
<b>Total</b>	<b>48.3</b> (36-62) <sup>a</sup>	<b>4.7</b> (1-17) <sup>a</sup>	<b>2.3</b> (0-5) <sup>ab</sup>	<b>7</b> (77.7%)	<b>Grade III</b> <b>11 (100%)</b>	<b>4</b> (44.4%)	<b>9</b> (100%)

<sup>a</sup> Mean value (range)

<sup>a</sup> Computed in patients who had reintervention

## RESULTS

Twenty patients with common bile duct strictures due to chronic pancreatitis were treated with self-expandable metal stent without elective stent removal in a ten year period (Table 1). Uncovered self-expandable metal stent (*u*SEMS) were used in 11 patients (3 females, 8 males) while 9 patients (3

females, 6 males) were treated with partially covered self-expandable metal stent (*c*SEMS). Mean age at self-expandable metal stent implantation was 48.7 (range: 31-69) years (*u*SEMS: 48.9 years; *c*SEMS: 48.3 years). Calcifications of the pancreas representing advanced chronic pancreatitis were present in all patients. Among *u*SEMS patients, 8 (72.7%) suffered from diabetes mellitus and 10 (90.9%) from severe

**Table 2.** Outcome data after self-expandable metal stent (SEMS) placement for common bile duct obstruction.

	Overall (n=20)	Uncovered ( <i>u</i> SEMS; n=11)	Covered ( <i>c</i> SEMS; n=9)	P value
<b>Follow-up; weeks</b>				
- Mean (range)	155 (25-412)	206 (52-412)	93 (25-233)	0.021 <sup>a</sup>
<b>Estimated stent patency; weeks</b>				
- Mean (range)	118 (25-412)	159 (52-412)	67 (25-150)	0.019 <sup>a</sup>
- Median	159	199	113	
<b>Reinterventions (RI)</b>				
- Patients with RI	9 (45.0%)	5 (45.5%)	4 (44.4%)	1.000 <sup>b</sup>
- Time to first RI: mean (range); weeks	119 (30-199)	146 (73-199)	86 (30-150)	0.020 <sup>a</sup>
<b>Complications</b>				
- Stent occlusion	7 (35.0%)	5 (45.5%)	2 (22.2%)	0.374 <sup>b</sup>
- Time to stent occlusion: mean (range); weeks	134 (49-199)	159 (52-412)	81 (49-113)	0.034 <sup>a</sup>
- Stent migration	2 (10.0%)	0 (0%)	2 (22.2%)	0.189 <sup>b</sup>
- Time to stent migration: mean (range); weeks	90 (30-150)	-	90 (30-150)	-
- Liver abscess	2 (10.0%)	1 (9.1%)	1 (11.1%)	1.000 <sup>b</sup>

<sup>a</sup> Log-rank test

<sup>b</sup> Fisher exact test

exocrine pancreatic insufficiency. Among *c*SEMS patients 4 (44.4%) had diabetes mellitus and all had severe exocrine insufficiency ( $P=0.175$  and  $P=0.479$  vs. *u*SEMS, respectively).

Mean follow-up for all patients was 155 (range: 25-412) weeks with mean stent patency of 118 (range: 25-412) weeks.

In *u*SEMS group follow-up was 206 (range: 52-412) weeks with mean stent patency of 159 (range: 45-412) weeks. Among patients treated with *c*SEMS, mean follow-up was 93 (range: 25-233) weeks and mean stent patency was 67 (range: 25-150) weeks (Table 2).

Stent patency was significantly longer in patients with *u*SEMS compared to *c*SEMS ( $P=0.019$ ) (Figure 1).

Stent migration (mean: 90 weeks; range: 30-150 weeks) occurred significantly earlier ( $P=0.042$ ) compared to stent obstruction (mean: 134 weeks; range: 49-199 weeks). Stent obstruction occurred significantly earlier ( $P=0.034$ ) in the *c*SEMS (2 patients: mean: 81 weeks; range: 49-113 weeks), compared to *u*SEMS (5 patients: mean 159 weeks; range: 52-412 weeks).

In 11 patients (55.0%) no reintervention was necessary; among 9 patients who needed reinterventions (*u*SEMS: 5/11, 45.5%; *c*SEMS: 4/9, 44.4%;  $P=1.000$ ), a mean of 4.4 reinterventions were necessary in the *u*SEMS and 2.3 in *c*SEMS patients. In the *u*SEMS group, all reinterventions occurred because of stent occlusion, in the *c*SEMS group 2 patients suffered from stent occlusion (22.2%) and 2 (22.2%) from stent migration. In both groups one patient suffered from hepatic abscess as a severe complication of stent occlusion (*u*SEMS: 9.1% vs. *c*SEMS 11.1%;  $P=1.000$ ).

**Individual Outcomes**

Four patients (2 *u*SEMS and 2 *c*SEMS) were treated on with plastic stents placed stent in stent after self-

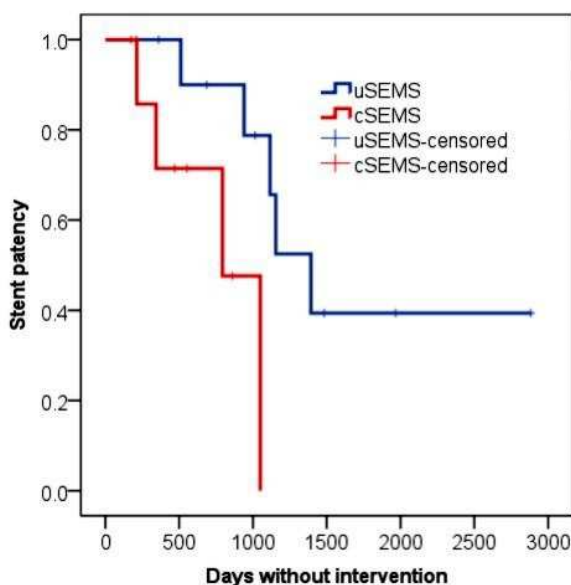
expandable metal stent occlusion. Among the 2 patients who suffered from occluded *c*SEMS, the stent could be extracted in one patient, but a biliary leak became apparent after stent extraction treated with another *c*SEMS. No further leakage was detected after the 3-month elective extraction. Another second occluded *c*SEMS could not be extracted, but prolapsed partially, causing ulceration of the opposing duodenal wall. After several attempts of extraction, the stent was trimmed endoscopically, a plastic stent was implanted in the remaining self-expandable metal stent and electively exchanged. In one case, after occlusion of *u*SEMS, a *c*SEMS was inserted. During further follow up this *c*SEMS was electively exchanged. Stent dislocation occurred in two patients with *c*SEMS, one into the duodenum, one into the proximal common bile duct. Both were rescued by gastroscopy or repositioned by endoscopic retrograde cholangiopancreatography, respectively.

**DISCUSSION**

Interventional endoscopy for treatment of common bile duct obstruction in patients with chronic pancreatitis is less invasive compared to surgery and offers excellent short-term effects. However the long-term outcome of surgery is superior. In most cases common bile duct obstruction is due to advanced chronic pancreatitis that needs definitive and long-term treatment. In this setting disadvantages of interventional endoscopy with plastic stent insertion are the necessity of scheduled stent exchange and a significant risk of stent clogging. However, self-expandable metal stent seems to combine advantages from both, interventional endoscopy and surgical treatment, by offering a less invasiveness larger stent diameter compared to plastic stents with the consequence of probably longer patency and therefore an increased long-term outcome.

We evaluated retrospectively the outcome of interventional endoscopy with insertion of self-expandable metal stent in patients with chronic pancreatitis. Two different types of self-expandable metal stent, covered and uncovered self-expandable metal stent, were used. During the first approximately 5 years of the observation period covered stents were not or not widely available, whereas later uncovered stents were selected for patients with gallbladder in situ to avoid obstruction of the cystic duct with an increased risk for cholecystitis. While a uncovered self-expandable metal stent became fixed due to tissue ingrowth it could not be extracted and therefore the use in benign diseases is relatively uncommon. Partially covered self-expandable metal stent, as used in our study, should offer the advantage of no, or at least less, tissue ingrowth with a longer patency. This hypothesis was not confirmed by our data.

Most of the data about stent patency exist from patients with malignant biliary obstruction. However, those data are not comparable to the situation in patients with chronic pancreatitis and common bile duct obstruction. In malignant diseases the limiting factor is patient survival, independently of stent function. A significant



**Figure 1.** Kaplan-Meier-plot of estimated stent patency. Stent patency was significantly longer in patients with *u*SEMS compared to *c*SEMS ( $P=0.019$ ).

longer life expectancy in benign diseases leads to advanced requirements on self-expandable metal stent, not achieved by the used self-expandable metal stent.

While the complication rates caused by *c*SEMS and *u*SEMS are not significantly different, there are unique complications in the two stent types. Clogging was the only problem in *u*SEMS (n=5; 45.5%), compared to *c*SEMS (n=2; 22.2%). If stent obstruction occurred due to tissue ingrowth or to reflux of dietary fibers, or a combination of both, is unclear. However, at least in the *c*SEMS group tissue overgrowth can be neglected and reflux of dietary fibers into stent, forming networks within the stent adjacent to the inner surface of the cover membrane, must be the main reason for stent obstruction.

The mechanism of reflux and obstruction are known from studies from van Berkel *et al.* [9]. From studies of Weickert *et al.* [28] with plastic stents we know about coating and the role of bacteria from the duodenal lumen for stent occlusion. The challenge for further developments on *c*SEMS is to avoid reflux or its attachment to the inner surface membrane of the stent. *c*SEMS became significant earlier occluded compared to *u*SEMS. We hypothesize that this is mostly due to the inner coating which attracts reflux and bacteria as described by Weickert *et al.* and Guaglianone *et al.* [28, 29].

Dislocation of a stent by migration can be only a problem of *c*SEMS (n=2; 22.2%). Migration is an early event. It occurs earlier compared to obstruction. This is probably caused by changes in the diameter of the stenosis, due to lesser infiltration by inflammatory cells. This could lead to a less fixed stent and is supported by our own findings, published elsewhere [15]. Approaches have been made to equipped *c*SEMS with plastic flaps and proximal/distal stent augmentations to prevent dislocation, but sufficient experience has not been gained yet. While this is only a complication of partially *c*SEMS, it leads to a significant increased complication rate for this stent type, which equalizes the advantages from the reduced number of obstructed stents due to less tissue ingrowth. We hypothesize that in fully covered stents this problem is also present.

A systematic review by van Boeckel *et al.* summarizes the existing data about plastic and metal stents for treatment of biliary obstruction with the conclusion that multiple plastic stents are superior to *u*SEMS for successful treatment of benign biliary obstruction. Success was defined as no need for further treatment and symptom relief [5].

Only a very few data regarding *c*SEMS are included in this paper. However, the conclusion that additional stent refinements are necessary before a general recommendation for *c*SEMS in benign common bile duct obstruction can be given, is supported by our findings.

Patients evaluated for self-expandable metal stent treatment generally have increased perioperative risks, reduced general state of health and elevated

comorbidity and therefore probably a reduced life expectancy. Therefore, they very often become stated a candidate for self-expandable metal stent, which is included in guidelines only as a backup modality [30]. Often self-expandable metal stent implantation is considered due to lack of established alternative concepts. But if common bile duct obstruction is resolved patients often gain life expectancy with the essential need of an effective long-term resolution of common bile duct obstruction. The main advantage of metal stents compared to plastic stent insertion is that fewer endoscopic retrograde cholangiopancreatography procedures are necessary to successfully treat common bile duct obstruction: Plastic stents have to be exchanged at least every three months. However, this possible advantage is wasted by a substantially reduced patency than expected, as shown in our study. If trimonthly scheduled stent exchanges are proposed, less invasiveness as one of the strongest advantages of self-expandable metal stent is neglected [26, 27].

## CONCLUSION

In patients with chronic pancreatitis, *u*SEMS had a longer patency than *c*SEMS. Complications (migration and occlusion) in patients treated with a *c*SEMS occurred earlier compared to *u*SEMS. It seems to be mostly a factor of the material of the inner surface membrane. The commercially available self-expandable metal stent, unfortunately, do not meet the demands of successful treatment of benign common bile duct stenosis. Further developments are necessary to define self-expandable metal stent an appropriate standard treatment for patients with common bile duct obstruction due to chronic pancreatitis. Until then patients should be strongly selected for self-expandable metal stent-treatment, realizing the risks of obstruction and migration.

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**Conflicts of interest** The authors have no potential conflict of interest

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