Specialised care in patients undergoing pancreateoduodenectomy

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Metal or plastic stents for preoperative biliary drainage in resectable pancreatic cancer

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ABSTRACT

Introduction
In pancreatic cancer, preoperative biliary drainage (PBD) with plastic stents increases complications compared to immediate surgery without PBD, as was demonstrated by a recent randomised controlled multicenter trial (RCT). The outcome of this RTC might be related to the type of stent used: a plastic endoprothesis. PBD is still frequently applied in case of extreme hyperbilirubinemia, logistical hurdles, need for additional preoperative diagnostics, and neoadjuvant therapy. Metal stents may reduce the risk of PBD-related complications.

Methods
A prospective multicenter cohort of patients with obstructive jaundice due to pancreatic cancer scheduled to undergo PBD before surgery was added to the study cohort of the earlier RCT (ISRCTN31939699). Treatment was performed according to the protocol of the original RCT with the exception that PBD was performed with a fully covered metal stent (fcSEMS). This newly added cohort of patients was compared to the plastic stent group of the original RCT for the primary outcome, i.e. PBD-related complications. A three-group comparison including early surgery patients was performed to compare overall complications.

Results
53 patients underwent PBD with a fcSEMS and were compared to patients treated with a plastic stent (n=102). Patients’ characteristics did not differ. PBD related complications rates were 24% in the fcSEMS group compared to 46% in the plastic stent group (relative risk (RR) of plastic stent use was 1.9, lower limit 90% confidence interval (CI) 1.2, P=0.006). Stent related complications (occlusion and exchange) were 6% in the fcSEMS group compared to 31% in the plastic stent group (RR of plastic stent use 5, lower limit 90% CI 1.9, P=0.001). Surgical complications were not significantly different between the fcSEMS and plastic stent group, 40% vs. 47%. In the three-group comparison overall complication rates for the fcSEMS, plastic stent and early surgery groups were resp. 51% vs. 74% vs. 39%.

Conclusion
For PBD in pancreatic cancer metal stents yield a better outcome compared to plastic stents. Although early surgery without PBD remains the treatment of choice, metal stents should be preferred over plastic stents whenever PBD is indicated.
INTRODUCTION

For decades there has been debate amongst gastroenterologists and surgeons as to whether jaundiced patients with a resectable periampullary or pancreatic tumor should undergo preoperative biliary drainage (PBD) to reduce postoperative morbidity and mortality associated with hyperbilirubinemia. With regard to the ongoing controversy between the benefits and adverse effects of PBD, a multicenter randomized controlled trial (RCT) (ISRCTN31939699) was conducted comparing a strategy of endoscopic PBD followed by surgery, with a strategy early surgery, which was published in 2010. Significantly more serious complications occurred in patients who underwent PBD (74%) compared to those who went for early surgery (39%). This difference in overall complication rate was largely due to a high rate of complications owing to PBD. In this regard, criticism towards the RCT concentrated on the technique of PBD; according to clinical practice at the time the RCT was performed plastic stents were used, while currently self-expandable metal stents (SEMS) are considered superior. Most studies reporting on the use of SEMS to relieve jaundice however, deal with non-surgical patients receiving palliative treatment. Studies on SEMS usage in surgical patients are limited, small and retrospective.

Notwithstanding the result of the RCT, extreme hyperbilirubinemia, logistical hurdles, necessity of additional diagnostics and increased use of neo-adjuvant treatment are valid indications to perform PBD. The answer to the question whether PBD should then be performed with plastic or metal stents lacks a high-level of evidence. However, to initiate randomized series comparing PBD with SEMS followed by surgery to surgery without PBD would cause ethical issues. In the original RCT the complication rate after PBD and surgery exceeded the rates reported after surgery only, therefore early surgery is now the standard preference, confirmed by a recent Cochrane review and meta-analysis. Initiating a new RCT, thereby withholding patients from the preferred treatment by assigning them to PBD with SEMS, would not have been ethical. First, the applicability of SEMS in the preoperative setting needs to be evaluated and validated.

We performed a prospective cohort study with patients undergoing selective PBD with SEMS and added this cohort to the previous RCT with identical inclusion criteria. The aim of the current study was to establish the superiority of SEMS during PBD as compared to the plastic stents, with respect to PBD related complications. In addition, overall outcomes after SEMS placement were then compared with perioperative outcomes after plastic stent placement and early surgery derived from the preoperative drainage vs. early surgery RCT.

METHODS

Study design

Patients with obstructive jaundice due to a resectable periampullary or pancreatic tumor scheduled to undergo PBD before curative resection were included. Early surgery was the standard
preference. Jaundiced patients were included and PBD was carried out only when early surgery was not appropriate or feasible: in case scheduling early surgery was not possible due to logistical hurdles (waiting list, referral pattern, diagnostics). These patients were treated with a fcSEMS to alleviate the biliary obstruction. In the previous RCT jaundiced patients with resectable pancreatic or periampullary tumors were randomized and assigned to either preoperative drainage followed by surgery or early surgery. In the present study, the fcSEMS cohort was added to the preoperative drainage vs. early surgery groups of the RCT. Inclusion criteria were identical to the criteria used in the RCT in order to create a similar cohort: serum bilirubin level of 40-250 µmol/l before inclusion or on the day of inclusion, computed tomography without evidence of distant metastases or extensive local tumor ingrowth into portal or mesenteric vessels (i.e. maximum 180 degrees of the circumference) and scheduled for surgical treatment in one of the participating centers. Patients over the age of 85 years, with a Karnofsky index <50%, who had undergone previous endoscopic or percutaneous PBD with stent placement, who were to receive neo-adjuvant chemotherapy or who suffered from severe gastric outlet obstruction were excluded.

Comparison was made between the current fcSEMS group and the historical RCT plastic stent group. This comparison was justified based on the similar inclusion criteria used. Through comparative inclusion criteria’s, baseline patient and operative characteristics were kept similar. Primary outcome measure was the PBD related complication rate.

**Study oversight**

This was a prospective multicenter cohort study conducted by the three regional and three academic hospitals that were also involved in the previous preoperative drainage vs. early surgery trial. A local study coordinator responsible for recruiting patients according to the inclusion criteria was appointed in every hospital. The local medical ethics committees of all participating hospitals approved the study design. This study was conducted according to the Declaration of Helsinki. The trial was registered at the Dutch Trial Register and was assigned the following number: NTR3142.

**Endoscopic preoperative biliary drainage and surgery**

In both academic and regional hospitals experienced gastroenterologists performed the endoscopic PBD by placing a fully covered biliary stent (WallFlex stent, Boston Scientific). Performing a papillotomy and the length of the fcSEMS was decided upon by the treating physician and tailored to the length of the stricture. The fcSEMS had already been frequently used in patients for palliative biliary drainage. Unsuccessful ERCP was followed by a second attempt or a percutaneous transhepatic cholangiography with biliary drainage. In line with the previous RCT, successful drainage was defined as a decrease of 50% of the serum bilirubin within two weeks following PBD. Surgery was performed in hospitals performing more than 20 resections per year according to the new regulations for pancreatic surgery in the Netherlands, being the same hospitals as in the preoperative drainage vs. early surgery RCT. Pylorus preserving pancreateoduodenectomy
or Whipple-Kausch pancreatoduodenectomy was performed in case no metastases or arterial involvement was evident. In case of (limited) portal venous involvement resection of the vein was performed 21,22. After resection a pancreaticojejunostomy (PJ), hepaticojejunostomy (HJ) and gastro- or duodenoenterostomy (GE) were performed. A silicon drain was placed near the PJ and HJ. If metastases or local unresectability were encountered during surgery, biopsies were taken and a palliative bypass procedure was performed. Definitive diagnosis was based on pathology examination of biopsies performed during surgery, the resection specimen or biopsies performed preoperatively.

**Evaluation of outcome**

Definition of complications and outcome parameters were equal to those in the preoperative drainage vs. early surgery RCT 20. The primary outcome parameter was the rate of (drainage related) complications after endoscopic PBD using fcSEMS during the interval period up to surgery. Secondary endpoints were overall complications up to 120 days after inclusion. These included PBD related complications and surgical complications being anastomotic leakage, intra-abdominal abscesses, delayed gastric emptying, wound infection, portal vein thrombosis, re-admission due to surgical complications, mortality and any complications requiring re-intervention. Complications other than the abovementioned were defined as complications outside protocol.

**Sample size and statistical analysis**

The expected PBD related complication rate when using SEMS was based on a meta-analysis of palliative drainage comparing covered and uncovered SEMS in non-surgical patients 23. Average complication rate of preoperative drainage by using SEMS was 26% and 46% by using a plastic stent, as derived from the RCT. SEMS were considered superior if the difference in complication rate was at least 20 percentage points. We used an exact test for single proportion with a one-sided significance level of 0.05 to test the null hypothesis that SEMS would lead to reduction of at least 20 percentage points. A 85% power to detect superiority of metal stents was achieved with 49 patients.

- Metal stent vs. plastic stent: A per-protocol comparison of the primary outcome PBD related complications between the fcSEMS cohort and the plastic stent cohort was performed using a one-sided chi-squared test P-values, 90% confidence interval and relative risks (RR) were given.
- Metal stent vs. plastic stent vs. early surgery: Comparison of secondary outcomes (overall complications) between fcSEMS group, plastic stent group and early surgery group was also performed using one-sided chi-squared test, with the connotation that the sample size was not powered to detect significant differences in this three-group comparison.

Kaplan-Meier estimates were used to depict the longitudinal incidence rate of complications during follow-up of both the fcSEMS and the plastic stent cohort. Categorical data were analyzed using chi-squared test, student T-test and Mann-Whitney U were used for analyzing continuous data. A logistic regression analysis was performed, adjusted for age, gender, body mass index,
biliary level and pathology, to denote the risk of PBD related complications in the fcSEMS group compared to the plastic stent group. A P-value of <0.05 was considered significant.

**RESULTS**

Between 2011 and 2013, 53 patients were screened for eligibility. Prior to any analysis, four patients were wrongfully included; they did not match the eligibility criteria. One patient was considered not resectable, one patient had severe comorbidity precluding operation and 2 patients were enrolled in a neo-adjuvant therapy protocol (NTR3709). The remaining 49 patients were included for analysis. Patients who underwent PBD with fcSEMS were compared to patients assigned to PBD with plastic stents (n=102) in the preoperative drainage vs. early surgery RCT. In this trial 202 patients underwent randomization, 102 patients were assigned to preoperative drainage followed by surgery and 94 patients underwent early surgery, 6 patients were excluded. Patients’ characteristics of both groups are depicted in Table 1. No differences were seen between the groups, although preoperative bilirubin was 176 μmol/L in patients with a fcSEMS vs. 154 μmol/L in patients who received a plastic stent (p=0.04). Papillotomy was performed in 53% of patients in the fcSEMS group and in 42% of patients in the plastic stent group. PBD with fcSEMS was performed successfully after the first attempt in 43 patients (88%), in three patients cannulation of the biliary duct was not achieved, a second ERCP was performed

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>SEMS cohort*</th>
<th>Plastic stent cohort#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (±SD)</td>
<td>67.5±8.1</td>
<td>64.7±10.5</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>29 (59)</td>
<td>49 (48)</td>
</tr>
<tr>
<td>BMI, (±SD)</td>
<td>25±3.5</td>
<td>25.2±3.9</td>
</tr>
<tr>
<td>Duration of symptoms, weeks (IQR)</td>
<td>4 (3-6)</td>
<td>3 (2-6)</td>
</tr>
<tr>
<td>Weight loss, kg (IQR)</td>
<td>5 (3-8)</td>
<td>5 (3-10)</td>
</tr>
<tr>
<td>Total bilirubin level, μmol/liter (±SD)</td>
<td>176±62.1</td>
<td>154±59.5</td>
</tr>
<tr>
<td>Diagnosis and cause of obstruction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td>47 (96)</td>
<td>92 (90)</td>
</tr>
<tr>
<td>Intraductal papillary mucinous neoplasm</td>
<td>1 (2)</td>
<td>-</td>
</tr>
<tr>
<td>Neuroendocrine tumor</td>
<td>-</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Benign lesions</td>
<td>-</td>
<td>9 (9)</td>
</tr>
</tbody>
</table>

*One patient refrained from surgery without definite pathology diagnosis.

#Derived from the the preoperative drainage vs. early surgery RCT trail: preoperative drainage vs. early surgery RCT. Normally distributed data are presented in means with standard deviation (SD), otherwise median and interquartile values are shown.
successfully using a fcSEMS (n=2), one patient received percutaneous transhepatic drainage. In the remaining three patients inadequate drainage despite the fcSEMS in situ was resolved by placement of an extra plastic stent (n=2) or an additional papillotomy (n=1). Time to surgery was 5.3 weeks and did not differ compared to patients in the plastic stent group, 5.2 weeks. After PBD, surgical exploration was performed in all but one patient who declined surgery. Eight patients who underwent PBD with metal stenting underwent palliative bypass (17%), the remaining 40 patients underwent resection. Resection was performed with the metal stent in situ. No perioperative problems were encountered due to the metal stent placement. Resection rate was higher compared to patients in the plastic stent group 83% vs. 56% (p=0.003).

**Metal stent vs. plastic stent**

PBD related complications occurred in 12 patients in the fcSEMS group (24%) compared to 47 patients in the plastic stent group (46%), with a RR of 1.9 (lower limit 90% CI 1.2, P=0.006). After adjustment for age, gender, body mass index, bilirubin level and pathology the odds of PBD related complications in the plastic stent group compared to the fcSEMS group was 3.5 (95% CI 1.5-8.3, P=0.004). The proportion of patients with PBD related complications is illustrated in Figure 1. Stent related complications were reported in 3 patients (stent occlusion and subsequent papillotomy (n=1), stent occlusion and subsequent exchange (n=1), stent dysfunction and exchange (n=1)) in the fcSEMS group (6%), compared to 31 patients in the plastic stent group (30%) (RR 5, lower limit 90% CI 1.9, P=0.001). PBD complications and complications related to surgery are depicted in Table 2. Post-ERCP pancreatitis occurred in nine patients after fcSEMS placement.

![Figure 1: PBD complications from date of inclusion up to surgery in jaundiced patients with resectable peri-ampullary or pancreatic cancer undergoing biliary drainage prior to surgery](image-url)
(18%), eight cases of mild and one severe pancreatitis. No differences were found between surgical complications in the metal and plastic stent group, i.e. 40% vs. 47%. In the fcSEMS group time to surgery in patients with PBD related complications was four days longer compared to patients without complications, in the plastic stent group there was a three day difference (median).

The secondary outcomes after PBD and surgery are shown in Table 3. Overall complications including PBD and surgical complications were lower in the fcSEMS group compared to the plastic stent group (p=0.003). Non-protocol complications, pre- and postoperative readmissions, and

Table 2 Pre- and postoperative complications reported in the SEMS cohort and the plastic stent cohort in the preoperative drainage vs. early surgery RCT

<table>
<thead>
<tr>
<th>Complications</th>
<th>SEMS cohort N=49, N (%)</th>
<th>Plastic stent cohort N=102, N (%)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Related to preoperative biliary drainage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any</td>
<td>12 (25)</td>
<td>47 (46)</td>
<td>0.006</td>
</tr>
<tr>
<td>Pancreatitis</td>
<td>9 (18)</td>
<td>7 (7)</td>
<td>0.016</td>
</tr>
<tr>
<td>Cholangitis</td>
<td>-</td>
<td>27 (26)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Perforation</td>
<td>1 (2)</td>
<td>2 (2)</td>
<td>0.487</td>
</tr>
<tr>
<td>Hemorrhage after ERCP</td>
<td>-</td>
<td>2 (2)</td>
<td>0.162</td>
</tr>
<tr>
<td>Related to stent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occlusion</td>
<td>2 (4)</td>
<td>15 (15)</td>
<td>0.027</td>
</tr>
<tr>
<td>Need for exchange</td>
<td>2 (4)</td>
<td>31 (30)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Related to surgery</td>
<td></td>
<td></td>
<td>0.169</td>
</tr>
<tr>
<td>Any</td>
<td>19 (39)</td>
<td>48 (47)</td>
<td></td>
</tr>
<tr>
<td>Pancreaticojejunostomy leakage</td>
<td>1 (2)</td>
<td>8 (8)</td>
<td>0.08</td>
</tr>
<tr>
<td>B</td>
<td>0</td>
<td>4 (4)</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>1 (2)</td>
<td>4 (4)</td>
<td></td>
</tr>
<tr>
<td>Hemorrhage after resection</td>
<td>2 (4)</td>
<td>2 (2)</td>
<td>0.217</td>
</tr>
<tr>
<td>Delayed gastric emptying</td>
<td>6 (12)</td>
<td>18 (18)</td>
<td>0.211</td>
</tr>
<tr>
<td>B</td>
<td>1 (2)</td>
<td>10 (10)</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>3 (6)</td>
<td>8 (8)</td>
<td></td>
</tr>
<tr>
<td>Hepaticojejunostomy leakage</td>
<td>1 (2)</td>
<td>1 (1)</td>
<td>0.292</td>
</tr>
<tr>
<td>Entero-jejunostomy leakage</td>
<td>2 (4)</td>
<td>4 (4)</td>
<td>0.476</td>
</tr>
<tr>
<td>Intra-abdominal abscess</td>
<td>2 (4)</td>
<td>2 (2)</td>
<td>0.217</td>
</tr>
<tr>
<td>Wound infection</td>
<td>7 (14)</td>
<td>13 (13)</td>
<td>0.379</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>2 (4)</td>
<td>9 (9)</td>
<td>0.147</td>
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<tr>
<td>Cholangitis</td>
<td>0</td>
<td>3 (3)</td>
<td>0.113</td>
</tr>
<tr>
<td>Myocardial infarct</td>
<td>0</td>
<td>4 (4)</td>
<td>0.08</td>
</tr>
<tr>
<td>Bowel ischemia</td>
<td>1 (2)</td>
<td>0</td>
<td>0.07</td>
</tr>
<tr>
<td>Need for relaparotomy</td>
<td>3 (6)</td>
<td>12 (12)</td>
<td>0.139</td>
</tr>
</tbody>
</table>

*Derived from the preoperative drainage vs. early surgery RCT  
*p-value one-sided chi-square test
mortality did not differ significantly. However, mortality due to any cause within 120 days after inclusion was 6% in the fcSEMS group and 15% in the plastic stent group (p=0.06). Hospital stay, including readmissions, was shorter in the fcSEMS group, 12 vs. 16 days.

### Metal stent vs. plastic stent vs. early surgery

To demonstrate the possible outcome when comparing the fcSEMS cohort with the early surgery cohort in the preoperative drainage vs. early surgery RCT, the early surgery group was added in Table 3. Overall complication rate was highest in patients who had undergone PBD with plastic stent (74%), compared to 51% and 39% in the fcSEMS group and early surgery group. The proportion of patients with overall complications, related to PBD and surgery, in the fcSEMS, plastic stent and early surgery groups is illustrated in Figure 2.

### DISCUSSION

This study compares the outcome after PBD with metal stents (fcSEMS) vs. plastic stent in jaundiced patients with a resectable pancreatic or periampullary tumor. fcSEMS are superior, PBD complications were reported in 25% as compared to 46% of patients who received a plastic stent. Stent related complications were observed in 6% vs. 30%, respectively. The risks of both PBD and stent related complications were lower in patients who received a fcSEMS. Overall complication rates were lower in the fcSEMS group compared to the plastic stent group owing to the low rate
Part I Preoperative biliary drainage in patients undergoing pancreatoduodenectomy

of PBD related complications. No differences in surgical complications were seen between the metal and plastic stent groups. PBD with fcSEMS was performed successfully in 43 patients (88%) at the first attempt and all patients were adequately drained after the first or a second attempt. No perioperative problems were encountered due to placement of the fcSEMS.

Post-stent placement pancreatitis occurred more frequently in the fcSEMS group, although eight out of nine patients suffered from mild pancreatitis. This has been described before; expansion of the metal stent may cause post-ERCP pancreatitis due to compression of the pancreatic duct orifice \(^{24}\). A papillotomy relieves the initial compression of the duct orifice when performed during ERCP. No differences were observed in papillotomy rates between the fcSEMS group and the plastic stent group. Despite a higher rate of post ERCP pancreatitis, differences in time to surgery between patients with and without PBD related complications was similar in the fcSEMS and plastic stent group.

The superiority of biliary drainage with fcSEMS is evident in this study. This was already established in patients with unresectable periampullary cancer. Two randomized trials comparing metal vs. plastic stents for palliation in patients with malignant biliary obstructions showed a longer patency, lower number of reinterventions and decreased overall treatment costs when using a metal stent \(^{25,26}\). In a systematic review by Moss et al. on the use of metal vs. plastic stents in the palliative setting it was concluded that SEMS are the devices of preferred choice \(^\circ\). Several studies are also available on PBD with SEMS in resectable patients and have reported good results \(^{12-18}\). However, studies were often small and retrospective reporting on a non-consecutive cohort of patients without comparison with a plastic stent. Furthermore, the type of SEMS used

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**Figure 2:** Overall complications (PBD and surgery related) reported in the SEMS cohort and the plastic stent and early surgery cohort in the preoperative drainage vs. early surgery RCT
can influence the interpretation of the available study results. A systematic review published in 2011 containing 11 studies comparing covered versus uncovered SEMS in jaundiced patients with unresectable disease reported a longer duration of patency of covered stents, which was defined as time to stent occlusion, and similar stent dysfunction rates. Two other meta-analyses did not find a benefit of covered over uncovered SEMS, although analyzing fewer studies compared to the abovementioned review, the same studies were included in both analyses. A clear preference can not be given.

A drawback of SEMS may be the relative high costs. However, due to additional re-admissions and stent exchanges due to occlusion of the much cheaper plastic stent, overall costs are similar when using plastic or SEMS, or even cost-saving in the latter. A recent RCT comparing plastic and metal stents in a palliative setting clearly showed that overall costs did not differ even in patients with a short drainage period. Therefore, considering the outcome of the existing literature and the present study, PBD should only be performed using a SEMS.

Despite its prospective and multicenter design, and the fact that it is based on a randomized trial cohort, the present study has limitations since the fcSEMS cohort was not part of the original RCT and newly included. This for one seems to be reflected in the resection and bypass rates, as more patients underwent resection in the fcSEMS cohort at which time a more aggressive surgical approach was used. This might also explain the higher 120-day mortality rate in the plastic stent group, together with the recent centralization of pancreatic surgery in the Netherlands, which is known to lead to lower mortality rates. Furthermore, these resection rates show no adverse effects of the use of fcSEMS.

This study design was chosen given the high PBD complication rates in the preoperative drainage vs. early surgery RCT and the results reported in the recent literature on metal stenting in a palliative setting. From an ethical point of view, performing a new RCT comparing fcSEMS followed by surgery with early surgery, and thereby withholding one group of patients from the current preferred treatment: early surgery, was not justified. Furthermore, one should realize when comparing the PBD first approach compared to early surgery, that the drainage related complication rate would always exceed in patients who undergo PBD and will not occur in patients who undergo early surgery without drainage. Although, no significant differences in complication rates were found between the fcSEMS group and early surgery group in this study, the sample size was not calculated based on overall complications since we were aiming to first evaluate and validate the use of metal stents during PBD. Potential benefits of PBD compared to early surgery could therefore not be proven. Additional clinical trials are needed to determine whether a shorter period of drainage might result in similar success rates but lower complication rates and which patients will benefit from the drainage-first approach; being those who suffer from severe jaundice, cholangitis, patients who need nutritious support or when early surgery is not feasible. Other ongoing studies in Sweden NCT00501176 and the United States NCT01191814, NCT01038713 are randomizing between plastic and metal stents. Although the current treatment of choice for most jaundiced patients with resectable pancreatic head cancer is early surgery without PBD, it
is not likely that all centers will be able to fully implement this regimen \(^7,34\). Therefore, PBD is still advised in a selection of resectable patients \(^3,6,19\). Our results strongly support the use of fcSEMS instead of plastic stents in patients in whom PBD is indicated.
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