Prolonged retention of prophylactic pancreatic stents is not associated with increased complications

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ABSTRACT

Objectives: The risk of post-ERCP pancreatitis (PEP) can be reduced effectively by the placement of a self dislodging pancreatic stent. The present study analyzed whether a prolonged interval until stent passage evaluation and removal of retained stents is associated with an increased risk for clinically relevant complications.
Methods: In the retrospective study 182 patients receiving a pancreatic stent for PEP prophylaxis were included and clinical data and complications until documented spontaneous stent dislodgement or removal were analyzed.
Results: The main indication for ERCP was choledocholithiasis (40.1%) followed by malignant stenosis (30.8%). Stent passage evaluation was performed in 34.1% at day 1—4, 23.6% at day 5—10, 17.6% at day 11—28 and 24.7% at day >28. PEP occurred in 13.1% of patients with no case of severe PEP. No association between PEP and day of stent passage evaluation (p = 0.719), retention of the pancreatic stent at time of evaluation (0.867) or prolonged stent retention >10 days (0.234) was observed. Only the duration of the procedure was associated with risk for PEP (p = 0.037). Besides PEP only one clinically relevant complication was observed in the cohort (0.5%) which was a late possibly stent related pancreatitis at day 9 after the procedure that resolved completely.
Conclusions: A prolonged interval for stent passage evaluation and stent retention is not associated with an increase of clinically relevant complications. A later evaluation and extraction of retained stents might be acceptable in selected cases where an additional endoscopic procedure can be saved due to a planned follow-up endoscopy.

Introduction

Pancreatitis is the most common complication of endoscopic retrograde cholangiopancreatography (ERCP). The incidence of post-ERCP pancreatitis (PEP) is about 3—4% with a mild or moderate course in 90% of cases [1—3]. Nevertheless, severe PEP remains a serious life-threatening condition with a mortality of 3% (95% CI 1.65%—4.51) [1]. Accordingly, several pharmacologic and procedure-related measurements have been established for PEP prophylaxis one being the placement of pancreatic duct stents in patients with high risk for PEP. The beneficial role of pancreatic stenting in the prophylaxis of PEP was demonstrated in large meta-analyses [4,5]. Especially severe PEP can be prevented almost completely by placement of a prophylactic pancreatic stent [6,7]. Accordingly, pancreatic stenting for patients with high risk for PEP is recommended by international guidelines [8—10]. Nevertheless, the ideal characteristics of pancreatic stents as well as the optimal duration of stent placement for PEP prophylaxis are not well defined. Generally, straight 5Fr polyethylene stents are used since they seem to be superior in the prevention of PEP and easier to place than 3Fr stents [11]. The used stents have a high potential of self dislodgment which is intentional as some smaller studies have reported a risk of pancreatic duct injury or pancreatitis by retained stents [12,13]. Although factors associated with stent retention or complications are not well defined international guidelines recommend the endoscopic removal of retained stents after 5—10 days based on this limited data [8—10]. The time interval until a prophylactic pancreatic stent is to be removed is of clinical relevance as many patients undergoing ERCP have planned endoscopic re-evaluations e.g. for biliary stent removal or replacement after the

initial procedure. In these patients removal of retained pancreatic stents together with the planned biliary procedure would save an additional radiologic evaluation of stent passage and endoscopic procedure for stent removal. Since this practice was frequently used in our endoscopic department, data of all consecutive patients that received prophylactic endoscopic stenting between January 2011 and June 2017 were analyzed retrospectively and followed until stent passage evaluation or stent removal. Aim of the study was to analyze whether a prolonged retention of prophylactic pancreatic stents is acceptable or associated with an increased complication rate. Additionally, remaining risk factors for PEP in this selected cohort of patients that already received PEP prophylaxis by pancreatic stenting were analyzed.

Patients and methods

The selection of the study cohort is illustrated in Fig. 1. In this retrospective study all consecutive patients that received a prophylactic pancreatic duct stent in the Frankfurt University Hospital, Germany between January 2011 and June 2017 were included. Inclusion criteria were (1) pancreatic stent placement for prophylaxis of PEP, (2) pancreatic stent in place at end of procedure and (3) follow up data until documented stent dislodgement or removal. A total of 388 patients that received an endoscopic pancreatic duct stent in our department between January 2011 and June 2017 were identified electronically by the procedural code. A total of 202 patients were included into the study that received the stenting for PEP prophylaxis of which 20 patients were excluded with missing follow up data (e.g. further treatment in another hospital). Accordingly, the study population consisted of 182 patients. Demographic data, lab values and follow up data were collected from the electronic patient files. All patients without contraindications received PEP prophylaxis with NSAIDs and/or hydration according to international guidelines [8]. PEP diagnosis and severity was established according to the modified consensus definition of PEP (clinical pancreatitis with lipase at least three times the upper limit of normal at more than 24 h after the procedure, requiring hospital admission or a prolongation of planned admission). Accordingly,
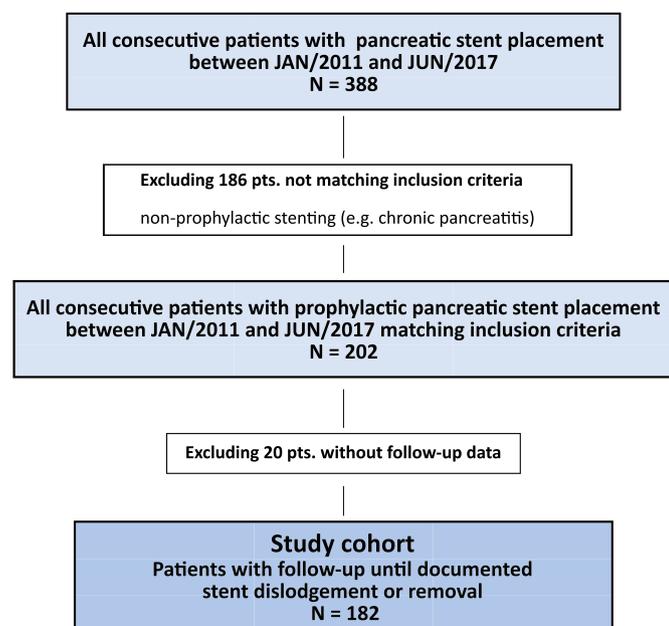
grading of pancreatitis was based on the need for hospital admission or prolongation of planned admission (mild PEP: 3 days, moderate PEP: 4—10 days, severe PEP: >10 days or complication like pseudocyst or need for drainage or surgery) [14,15]. Any complication associated with the pancreatic stent requiring intervention or prolongation of hospitalization were documented as clinically relevant (i.e. pancreatitis, inward stent dislodgement, infection, perforation). The duration of the procedure was defined as the time from the insertion of the endoscope until removal of the endoscope in minutes. A cut-off of 10 days to differentiate between early and late stent passage evaluation was used since international guidelines recommend the endoscopic removal of retained stents not later than 10 days [8—10].

The study was approved by the institutional review board of the Frankfurt University Hospital.

Statistical analysis

Data collection, data management, and statistical analyses were performed with SPSS software package, release 17.0 (SPSS Inc., Chicago, IL). Differences between groups were determined using nonparametric Wilcoxon-Mann-Whitney test. For the multivariate regression analysis to identify factors associated with post-ERCP pancreatitis a backward stepwise logistic regression model was used. In the backward stepwise logistic regression model variables with p values > 0.10 were eliminated from the model.

For the cox regression model spontaneous stent dislodgment was considered as event. The time in the study was defined as time from ERCP procedure until stent passage evaluation. An univariate Cox regression hazard model was used to identify predictors of stent retention. For the assessment of independent predictors of stent dislodgement a multivariate Cox regression with backward stepwise likelihood ratio was performed. P- values < 0.05 were considered statistically significant.

Results

Pancreatic stents

All placed pancreatic stents were 5Fr polyethylene stents with a single external flap and no internal flange. The predominantly used stent lengths were 5 cm (121/182, 66.5%) and 6 cm (46/182, 25.3%), Table 1.

Patient population

The demographic and clinical characteristics of the study cohort are displayed in Table 1. The most frequent indication for the ERCP procedure was choledocholithiasis (73/182, 40.1%) followed by malignant stenosis of the bile duct (56/182, 30.8%) and biliary anastomotic stenosis after liver transplantation (23/182, 12.6%). Endoscopic papillotomy was performed in the majority of cases (173/182, 95.1%). Contrast injection in the pancreatic duct was performed (intentionally or unintentionally) in half of the cases (91/182, 50.0%). A biliary stent was placed during the same procedure as the pancreatic stent in 65.9% of patients (120/182). Post-ERCP pancreatitis was observed in 13.2% of patients (24/182) with 9.9% (18/182) mild, 3.3% (6/182) moderate and no severe cases of pancreatitis. Stent passage evaluation was performed after a median of 7 days. At that time point stent retention was documented in 59.9% of cases (109/182). In almost all cases the evaluation of stent passage was performed endoscopically (179/182, 98.4%) and retained stents removed during the same procedure. Only one possibly stent related complication was documented (1/182, 0.5%). This single patient experienced a mild pancreatitis at day 9

Fig. 1. Selection of the study cohort. A total of 182 patients were included in the final analyses.

Table 1
Demographics of the study cohort by time of evaluation of stent passage.

	All N = 182	Early (day 1–10) N = 105	Late (>day 10) N = 77	p-value
Age (years)	61 (14–88)	60 (20–83)	63 (14–88)	0.464
Male gender	109 (59.9)	62 (59.0)	47 (61.0)	0.879
ERCP indication				**0.014**
Choledocholithiasis	73 (40.1)	46 (43.8)	27 (35.1)	
Malignancy	56 (30.8)	37 (35.2)	19 (24.7)	
Biliary anastomotic stenosis	23 (12.6)	8 (7.6)	15 (19.5)	
Bile leakage	18 (9.9)	7 (6.7)	11 (14.3)	
Prim. sclerosing cholangitis	12 (6.6)	7 (6.7)	5 (6.5)	
Lab values prior to procedure				
Bilirubin (mg/dl)	2.6 (0.2–30.2)	3.4 (0.2–30.2)	1.4 (0.3–29.7)	**0.042**
Alkaline phosphatase (U/l)	216 (34–2369)	233 (41–2369)	199 (34–1578)	0.167
Lipase (U/l)	50 (8–20811)	54 (8–20811)	46 (12–6290)	0.362
Papillotomy	173 (95.1)	98 (93.3)	75 (97.4)	0.306
Pre-cut papillotomy	11 (6.0)	8 (7.6)	3 (3.9)	0.360
Duration of procedure (min)	57 (12–186)	55 (12–186)	61 (20–180)	0.307
First-time ERCP	159 (87.4)	91 (86.7)	86 (88.3)	0.824
Pancreatic contrast injection	91 (50.0)	47 (44.8)	44 (57.1)	0.133
Duodenal diverticulum	12 (6.6)	5 (4.8)	7 (9.1)	0.365
Simultaneous bile duct stenting	120 (65.9)	61 (58.1)	59 (76.6)	**0.011**
OLT	23 (12.6)	8 (7.6)	15 (19.5)	**0.023**
Diabetes	31 (17.0)	16 (15.2)	15 (19.5)	0.549
BMI (kg/m^2)	25 (16–44)	25 (16–44)	25 (19–35)	0.627
Post-ERCP pancreatitis	24 (13.2)	11 (10.5)	13 (16.9)	0.268
mild	18 (9.9)	7 (6.7)	11 (14.3)	
moderate	6 (3.3)	4 (3.8)	2 (2.6)	
severe	0 (0)	0 (0)	0 (0)	
Pancreatic stent length (all 5Fr)				**0.006**
3 cm	5 (2.7)	4 (3.8)	1 (1.3)	
5 cm	121 (66.5)	59 (56.2)	62 (80.5)	
6 cm	46 (25.3)	34 (32.4)	12 (15.6)	
7 cm	10 (5.5)	8 (7.6)	2 (2.6)	
Possible stent related complications until removal	1 (0.5)[a]	1 (1.0)	0 (0)	1.0
Stent passage evaluation				0.575
Endoscopic	179 (98.4)	104 (99.0)	75 (79.4)	
Radiologic	3 (1.6)	1 (1.0)	2 (2.6)	
Elective stent evaluation	171 (94.0)	98 (93.3)	73 (94.8)	0.762
Time until evaluation of stent passage (days)	7 (1–144)	4 (1–10)	29 (11–144)	–
1-4d	62 (34.1)	62 (59.0)	–	
5-10d	43 (23.6)	43 (41.0)	–	
11-28d	32 (17.6)	–	32 (41.6)	
>29d	45 (24.7)	–	45 (58.4)	
Stent retention at time of evaluation	109 (59.9)	66 (62.9)	43 (55.8)	0.362

Continuous parameters are expressed as medians with range, nominal parameters as number of patients with percentage of occurrence. Differences between groups (early vs. late) were evaluated by Mann-Witney-U test. Significant p-values <0.05 are highlighted in bold.

[a] Mild pancreatitis with elevation of lipase and abdominal pain at day 9.

(increase of serum lipase and abdominal pain) that resolved rapidly after removal of the pancreatic stent.

Differences between patients with early (d1-10) and late (>d11) stent passage evaluation

Differences between patients with early (d1-10) and late (>d11) stent passage evaluation are shown in Table 1. Most parameters did not differ significantly between both groups. Especially the complication rate was similar in both groups. Neither the rate of post-ERCP pancreatitis (early: 10.5% vs. late: 16.5%, p = 0.268) nor the rate of other complications during the follow-up time (only one case of late pancreatitis at day 9, 0.5%, late: 0%) differed significantly between the early and late evaluation group. The indication for the ERCP differed significantly between both groups with more cases of biliary anastomotic stenosis and bile leakage and less cases of choledocholithiasis and malignant stenosis in the late evaluation group (p = 0.014). Accordingly, simultaneous stenting of the bile duct was less frequent in the early evaluation group (58.1% vs. 76.6% mg/dl, p = 0.011). The percentage of retained stents did not differ significantly between the groups (62.9 vs. 55.8%, p = 0.362).

Stent retention and association with covariates

The percentage of retained stents was high even when the stent passage evaluation was later than day 28. The findings are illustrated in Fig. 2. The rate of retained stents was 72.6% in the patient
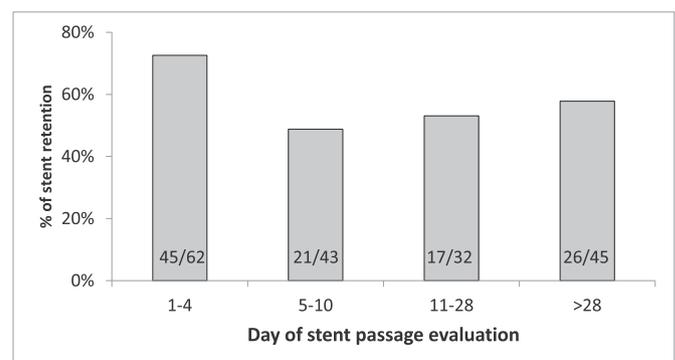
Fig. 2. Percentage of retained pancreatic stents according to time of evaluation of stent passage.

Table 2
Factors associated with early stent dislodgement.

|	Univariate analysis		Multivariate analysis	
	Hazard ratio (95% CI)	p-value	Hazard ratio (95% CI)	p-value
Age (years)	0.991 (0.977–1.006)	0.242		
Male gender	1.271 (0.777–2.080)	0.340		
Papillotomy	0.555 (0.201–1.533)	0.256		
Pre-cut papillotomy	1.145 (0.358–3.659)	0.823		
Duodenal diverticulum	0.277 (0.068–1.133)	0.074		
Pancreatic contrast injection	0.713 (0.449–1.133)	0.152		
Simultaneous bile duct stenting	0.545 (0.324–0.917)	0.022	0.562 (0.324–0.975)	0.040
OLT	0.899 (0.472–1.713)	0.746		
BMI (kg/m^2)	1.037 (0.981–1.096)	0.201		

OLT, orthotopic liver transplantation.
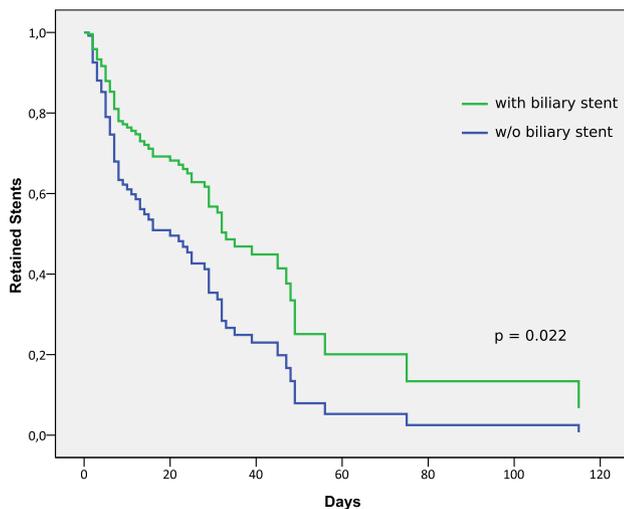
Fig. 3. Retained pancreatic stents over time in patients with and without simultaneous biliary stent. Analyses and plot by cox regression model.

trend for an association with longer stent retention was observed for the presence of a duodenal diverticulum (HR 0.277, 95% CI 0.068–1.133, p = 0.074). Accordingly, in the multivariate model only the presence of a biliary stent was associated independently with longer pancreatic stent retention (HR 0.562, 95% CI 0.324–0.975, p = 0.040). Fig. 3 illustrates the cox regression plot for patients with and without a simultaneous biliary stent.

Risk factors for post-ERCP pancreatitis

To determine which factors are associated with the development of post-ERCP pancreatitis in this cohort of patients with pancreatic stenting a logistic regression model was used. Results are summarized in Table 3. In the analyses only the duration of the procedure was associated significantly with the development of post-ERCP pancreatitis (OR 1.012, 95% CI 1.001–1.024, p = 0.037) while orthotopic liver transplantation (OLT) showed a statistical trend (OR 2.765, 95% CI 0.965–7.917, p = 0.058).

Discussion

The present study is to our knowledge the first to analyze whether a prolonged interval for stent passage evaluation of prophylactic pancreatic stents is associated with clinically relevant complications. The main finding of the study is that overall clinical complications associated with prophylactic pancreatic stenting are rare and not associated with prolonged stent retention.

The study reports a rate of PEP of 13.2% which is in keeping with published data on patient cohorts that received prophylactic pancreatic stenting [4]. No case of severe PEP was observed

group with stent passage evaluation at day 1–4, 48.8% in the evaluation group at day 5–10, 53.1% at day 11–28 and 57.8% later than day 28.

The results are summarized in Table 2. In the univariate model the presence of a simultaneous bile duct stent was associated with a longer retention of the pancreatic stent (Hazard ratio for stent dislodgement 0.545, 95% CI 0.324–0.975, p = 0.022). A statistical

Table 3
Factors associated with post-ERCP pancreatitis.

	No pancreatitis	post-ERCP pancreatitis	Odds ratio (95% CI)	p-value
Age (years)	62 (14–88)	54 (20–79)	0.977 (0.950–1.004)	0.096
Male gender	96 (60.8)	13 (54.2)	0.763 (0.322–1.811)	0.540
Papillotomy	151 (95.6)	22 (91.7)	0.510 (0.100–2.613)	0.419
Pre-cut papillotomy	9 (5.7)	2 (8.3)	1.505 (0.305–7.427)	0.616
Duration of procedure (min)	57 (12–186)	60 (34–174)	1.012 (1.001–1.024)	**0.037**
Experience level of examiner <5yrs	45 (28.5)	3 (12.5)	0.359 (0.102–1.262)	0.110
First-time ERCP	136 (86.1)	23 (95.8)	3.721 (0.478–28.963)	0.210
Pancreatic contrast injection	77 (48.7)	14 (58.3)	1.455 (0.610–3.471)	0.391
Simultaneous bile duct stenting	107 (67.7)	13 (54.2)	0.563 (0.236–1.344)	0.196
OLT	17 (10.8)	6 (25.0)	2.765 (0.965–7.917)	0.058
Diabetes	27 (17.1)	4 (16.7)	0.963 (0.305–3.044)	0.949
BMI (kg/m^2)	25 (17–44)	23 (16–35)	0.959 (0.857–1.0752)	0.462
Stent retention at time of evaluation	95 (60.1)	10 (41.7)	0.928 (0.388–2220)	0.867
Retained stent at day >10	35 (22.2)	8 (33.3)	1.757 (0.695–4.445)	0.234
Time until evaluation of stent passage (days)	7 (1–144)	12 (2–56)	1.004 (0.983–1.025)	0.719

Continuous parameters are expressed as medians with range, nominal parameters as number of patients with percentage of occurrence. Analyses by logistic regression model.
Significant p-values <0.05 are highlighted in bold.

underlining that it can be prevented reliably by pancreatic stent placement [6,7]. The rate of late complications possibly associated with the pancreatic stent was overall very low with only one case of mild pancreatitis at day 9 after ERCP. No differences were observed regarding the rate of late complications between the groups with early and late stent passage evaluation. Even the retention of stents >28 days which after all was the case in 19 cases did not cause clinically evident complications. The existing data on late complications associated with longer stent retention is very limited. One small study on 61 patients from 1996 examined the frequency of pancreatic duct irregularities after removal of the pancreatic stent reporting stent-induced ductal changes in about 80% of cases. Explicitly no association between stenting duration and frequency of stent-induced ductal changes was reported and long-term resolution of the changes was documented in the majority of cases [13]. Interestingly, this study more than 20 years ago comes to the conclusion that the use of pancreatic stents should remain largely experimental [13]. One other study found an association between pancreatic stent retention >14 days and PEP with a relative risk for PEP of 5.2 [16]. Still, it is debatable whether the association is causal as PEP occurred in the first 1–4 days after ERCP and thus could hardly be caused by prolonged stent retention >14 days. In the present study stent retention >10d was not associated with PEP although the incidence was higher in the PEP group. It can be assumed that the pancreatic edema during PEP itself might impede spontaneous stent dislodgment thus being not causal for the development of PEP. The European guideline on the prevention of PEP based its recommendation to remove retained pancreatic stents between day 5 and 10 after placement on the two mentioned studies [8,9]. Although this recommendation is reasonable for most patients the present study suggests that a longer interval might be acceptable for selected patients as clinically relevant complications are not to be expected. In our clinical experience especially patients that require follow-up endoscopic procedures e.g. for biliary stent removal or replacement an additional radiologic evaluation or endoscopic procedure can be saved when retained stents are removed during the planned follow-up endoscopy. The use of pancreatic stents with even longer replacement intervals of more than 12 weeks is successfully used in patients with chronic pancreatitis and pancreatic duct strictures. However, at least 7Fr stents are commonly used hereby [17–19].

The present study analyzed factors associated with prolonged stent retention. To date, the only factors associated with stent retention are stent length, diameter and presence of flags or pig tails [12,16]. Since the used stents in the present study were of the same diameter and similar length, stent-related parameters could not be included into the analyses. We report an independent association of simultaneous presence of biliary stents with retention of the pancreatic stents. One possible explanation is that biliary and pancreatic stents are wedged in the papillary region impeding spontaneous stent dislodgment by the mechanical interaction. As suggested it seems acceptable to remove retained pancreatic stents together with planned replacement or removal of the biliary stents.

In the present cohort of patients with pancreatic stenting only the duration of the procedure was associated with an increased risk for PEP (OR 1.012 per minute duration) which in general can be used as a surrogate for difficult conditions with probably more cannulation attempts. Obviously in this cohort with high risk for PEP requiring pancreatic stent placement other risk factors are of less importance.

Limitations of this study are the retrospective design and relatively small cohort. Additionally, only clinically evident complications were documented allowing no conclusion on possible pancreatic duct changes by prolonged stent retention. Since the study addresses clinically relevant questions on a field with very limited data these limitations are acceptable until prospective data or larger cohorts are available.

In conclusion, the present study suggests that a prolonged interval for stent passage evaluation and thus a prolonged retention of prophylactic pancreatic stents is not associated with an increase of clinically relevant complications. Accordingly, a later evaluation and extraction of retained stents might be acceptable in selected cases where radiologic evaluation or an additional endoscopic procedure can be saved due to a planned follow-up endoscopy e.g. for biliary stent replacement.

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