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Adverse Event Severity Grading System Applied to Percutaneous Transhepatic Biliary Metal Stenting as A One- or Two-Stage Procedure in Patients with Unresectable Malignant Extrahepatic Bile Duct Obstruction

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1. Abstract

1.1. Aims: Percutaneous transhepatic biliary stenting (PTBS) can be associated with adverse events (AEs) of different severities. AEs might be assessed by a standardized AE severity grading system. The aim of this study was to compare the severity of adverse events in the 30-day interval after PTBS as a one- or two-stage procedure in patients with nonresectable malignant extrahepatic bile duct obstruction.

1.2. Methods: This was a retrospective, single-center, comparative study (NCT04992585) including prospectively collected data on all PTBSs between 2008 and 2021. Follow up was documented for up to 5 years. Adverse events (AEs) in the 30-day interval were assigned as mild (=1), moderate (=2), severe (=3) or fatal/death (=4) according to definitions of the ASGE AE severity grading system.

1.3. Results: In the defined study period, 39/102 patients with percutaneous biliary interventions received an equally successful metal stent in a one-stage (n= 23) or two-stage (n=16) procedure. The severity of AEs was as follows: one-stage PTBS (9/23 = 39.1%): 1 (n= 1), 2 (n=3), 3 (n=1), and 4 (n=3); and two-stage PTBS (6/16 = 37.5%): 1 (n=5), 2 (n=1), 3 (n=0), and 4 (n=0). The difference in the severity of AEs was significant (p=0.0252), favoring two-stage PTBS. Overall survival in patients with one-stage PTBS (139.8 (SE +/- 43.4) days) and two-stage PTBS (403.3 (SE +/- 94.6) days) differed as well (p=0.0065).

1.4. Conclusion: The ASGE AE severity grading system was applied to PTBS for the first time. Two-stage PTBS might be favored over one-stage PTBS in terms of AEs.

2. Introduction

Percutaneous transhepatic biliary interventions (PBIs) are used in biliary tract diseases when endoscopic access is not successful or not possible due to anatomical changes after abdominal surgery [1-3]. However, failed biliary cannulation by ERCP is a rare event and does not exceed 5% in expert centers [4]. Self-expandible metal stents (SEMSs) are percutaneously implanted in patients with malignant extrahepatic bile duct obstruction for an extended period of time [5]. In this setting, Percutaneous Transhepatic Biliary Stenting (PTBS) is usually performed as a two-step procedure with Percutaneous Transhepatic Biliary Drainage (PTBD) of the accumulated bile fluid by an external or an external/internal plastic catheter in the first step and metal stent implantation at an interval of a few days in the second step [6]. Endoscopic ultrasound-guided biliary drainage (EUS-BD) [7] is an increasingly used alternative method to percutaneous transhepatic biliary drainage (PTBD), and a recently published meta-analysis on EUS-BD versus two-stage PTBD concluded that

EUS-BD might be favored over PTBD in terms of clinical success and adverse events [8, 9], although prospective studies are still lacking that compare both interventions in their best possible performance. PTBS as a one-step procedure is similar to EUS-BD with metal stenting, as no internal/external or external catheter remains in the patient at the end of the procedure, and the stay in the hospital is shorter than in two-stage PTBS [10, 11]. However, it is not clear whether one-stage PTBS indeed shows fewer adverse events than two-stage PTBS. The aim of this study was to retrospectively analyze the prospectively collected data of one-stage and two-stage PTBS in patients with proximal and distal malignant bile duct obstruction in terms of adverse events. Adverse events in PBIs might range from very mild to fatal [12]. Therefore, a standardized AE severity grading with four levels was applied [13].

3. Patients and Methods

This registered study (NCT04992585) was approved by the local Institutional Review Board. The prospectively collected data of all percutaneous biliary interventions (PBIs) between July 2008 and July 2021 were retrospectively screened for inclusion in the study. Adult patients with unresectable malignant extrahepatic bile duct obstruction who had received one-stage or two-stage PTBS met the inclusion criteria. PBI with Rendezvous-ERCP and endoscopic metal stent insertion was excluded. One-stage PTBS was defined as a PBI with metal stenting and removal of all catheters in the first session. Two-stage PTBS was defined as metal stenting at an interval of at least one day after an external or external/internal drainage catheter was inserted into the bile duct system (Figure 1). Usually, the time interval between the first PBI and metal stenting is 1–7 days. The technique of one-stage or two-stage PTBS with or without endoscopic control of stent release was previously described in detail [8]. All patients received intravenous administration of peri-interventional antibiotic prophylaxis with 2 g cetriaxone and 3 x 500 mg metronidazole as well as 25 – 50 mg petidine when dilation of the transhepatic tract was performed. Covered and noncovered self-expandable metal stents 8–10 mm x 60–100 mm in size (Bonastent®, Taewoong, South Korea; Wallflex®, Boston Scientific, USA) were used depending on the length and localization of the bile duct stenosis. Clinical success of biliary stenting was assessed by the serum total bilirubin level in mg/dl on the day of the first technically successful PTBD in two-stage PTBS or technically successful one-stage PTBS and at the follow-up 3 and 7 days after the intervention. AEs, including all deaths, were documented in the follow-up 30 days after the first PTBD and were retrospectively classified as mild, moderate, severe, and fatal/death according to the severity grading system of the American Society of Gastrointestinal Endoscopy (ASGE) (Table 1) [13]. In two-stage PTBS, AEs of performed PTBS and previous PTBDs were summarized in AE analysis per patient. The investigators assigned the numbers 0–4 to the AE severity grades for weighted statistical calculation: none = 0, mild = 1, moderate = 2, severe = 3, fatal/death = 4. The association between intervention and AE was always classified as proven, probable, possible, unlikely, no, and not assessable. Only proven, probable or possible associations were considered for calculation. Furthermore, stay in hospital after the first technically successful PTBD in two-stage PTBS or technically successful one-stage PTBS in days, rate of biliary reinterventions per patient, rate of received medical oncological therapy after biliary drainage and overall survival in days in the follow-up of up to five years were calculated. Medical oncological therapy included standard chemotherapy protocols using gemcitabine, gemcitabine/nab-paclitaxel, FOLFIRINOX, FOLFIRI, 5-FU, gemcitabine/cisplatin, FLO, and cisplatin/etoposide. Specified medical oncological therapy was not further considered in the results section. Biliary reintervention was defined as any unscheduled endoscopic or percutaneous biliary intervention that was necessary for recurrent bile duct obstruction during follow-up after technically successful PTBS.

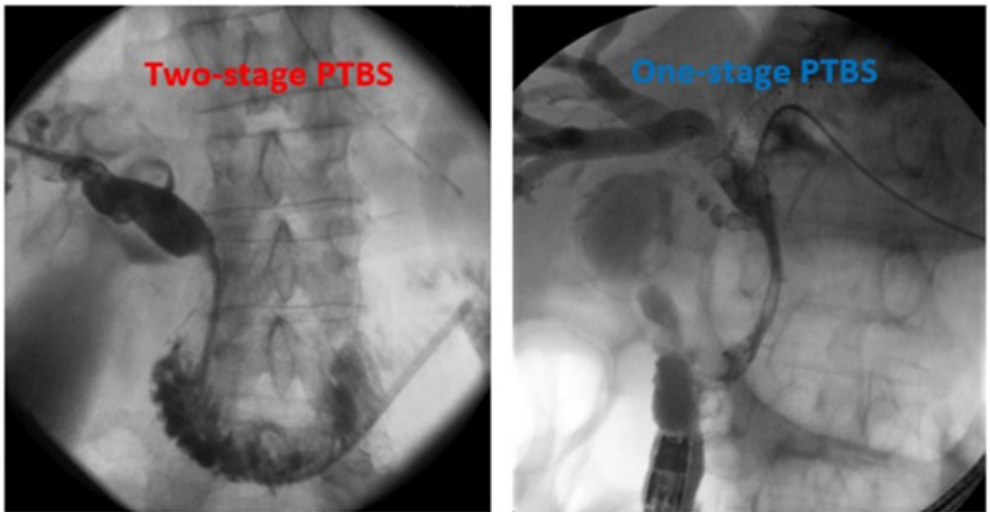


Figure 1: Case examples of one-stage PTBS (blue) or two-stage PTBS (red): The left image shows a ride-sided percutaneous transhepatic biliary intervention with a primarily inserted internal/external catheter before metal stent implantation in interval. The right image shows a left-sided percutaneous transhepatic biliary intervention with a primarily inserted metal stent and the tip of an endoscope by which stent release is visually controlled.

Table 1: Recommend AE severity grading system of the American Society of Gastrointestinal Endoscopy (ASGE).

	Severity Grade			
Consequence of adverse event	**mild**	**moderate**	**severe**	**fatal**
Procedure aborted (or not started) because of an adverse event	x			
Unplanned anaesthesia/ventilation support, i.e. endotr. intubation during conscious sedation*		x		
Unplanned admission or prolongation of hospital stay for up to 3 nights	x			
Prolongation of hospital stay for 4-10 nights		x		
Prolongation of hospital stay for > 10 nights			x	
Intensive care unit admission for 1 night		x		
Intensive care unit admission for > 1 night			x	
Blood transfusion		x		
Further endoscopic or percutaneous transhepatic intervention necessary (e.g. for haemostasis)		x		
Radiological intervention necessary (e.g. for coiling)		x		
Surgical intervention necessary			x	
Permanent damage/permanent disability remains			x	
Death				x

4. Statistics

All statistical calculations were completed by the Department of Medical Statistics and Biomathematics of Mannheim University Hospital (University of Heidelberg) with SAS software, release 9.4 (SAS Institute Inc., Cary, North Carolina, USA). For qualitative factors, absolute and relative frequencies are given. For quantitative variables, approximately normally distributed mean values and SDs were calculated. For skewed or ordinal data, medians together with minima and maxima are presented. To compare the two groups regarding a binary factor, a chi-square test was performed. If the conditions of this test were not fulfilled, Fisher's exact test was used instead. The mean values of two groups were compared by two-sample t-tests (in the case of normally distributed data) or the Mann–Whitney U-test. Survival curves were generated by the Kaplan–Meier method. Comparison of the Kaplan–Meier curves was performed with the log rank test. In general, the result of a statistical test was considered significant if the corresponding P value was less than 0.05.

5. Results

In the defined period, 234 PBIs were performed in 102 patients. Thirty-nine of these 102 patients received one-stage (n=23) or two-stage (n=16) PTBS. All PTBS procedures were technically successful, at least the second attempt. Patients and PTBS characteristics are shown in (Table 2). In one-stage PTBS, 9 AEs occurred in 23 patients: 9/23 (39,1%). The summarized ASGE AE score was 22/9 patients. In two-stage PTBS, 6 AEs occurred in 16 patients: 6/16 (37.5%). The summarized ASGE AE score was 7/6 patients. All AEs in the interval of 30 days after the first PBI per patient are shown in detail in (Table 3). The frequency of AEs in one-stage PTBS was nearly equal to that in two-stage PTBS (p= 0.1017). However, the severity of the documented AEs was significantly lower in two-stage PTBDs than in one-stage PTBDs (p= 0.0252). There was no significant difference in the mean total serum bilirubin level before (10.2 (0.4–35.2) versus 11.7 (3.3–22.9) mg/dl, p= 0.1487) or 3 (5.8 (0.6–18.6) versus 7.6 (3.7–18.5) mg/dl, p= 0.3204) and 7 (4.9 (0.4–13.7) versus 4.5 (0.8–13.3) mg/dl, p = 0.7090) days after successful biliary drainage of extrahepatic bile duct obstruction in either group (Figure 2). As expected, the mean hospital stay was longer in two-stage PTBS (19,3 (95% CI: 12.6–25.9) days) than in one-stage PTBS (12,6 (95% CI: 8.9–16.2) days): p = 0.1499. Furthermore, the proportion of patients who received medical oncological therapy for the underlying malignant disease was very similar in one-stage PTBS (7/23=30.4%) and two-stage PTBS (5/16=31.3%), whereas the overall survival probability differed significantly between one-stage PTBS (139.8 (SE +/- 43.4) days) and two-stage PTBS (403.3 (SE +/- 94.6) days): p=0.0065 (Figure 3). The cause of death was mainly associated with underlying tumor disease in one-stage PTBS in 16/23 (69.5%) patients and in two-stage PTBD in 11/16 (68.7%) patients. A total of 1/16 (6.2%)

patients in two-stage PTBS and 7/23 (30.4%) patients in one-stage PTBS died in the 30-day interval after intervention. Two of these seven deaths had a possible association with the intervention, and one death with resuscitation during the intervention had a probable association with the intervention. A postmortem examination was denied by the relatives in this case. However, fatal lung embolism in advanced metastasized renal cell carcinoma was assumed to be the most likely cause of death. The mean biliary reintervention rate per patient correlated with one-stage PTBS (0.21 (range 0–4)) and two-stage PTBS (0.69 (range 0–3)) with the respective overall survival probability (p = 0.0381).

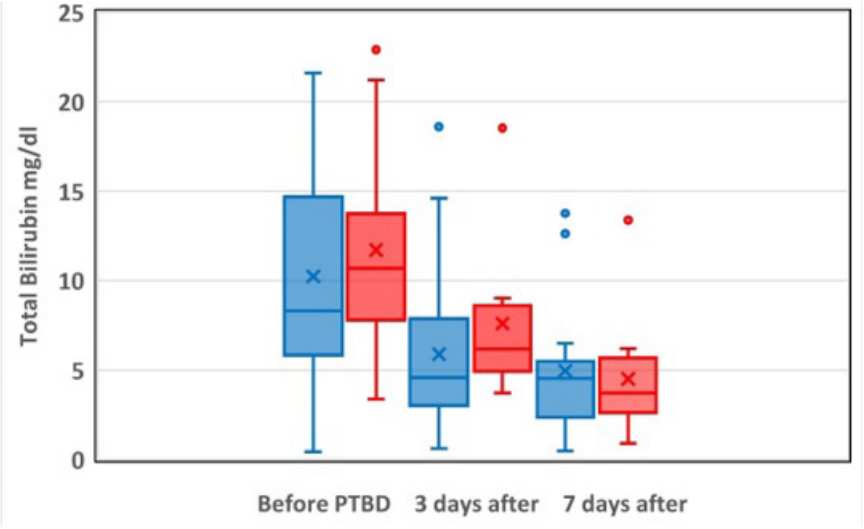
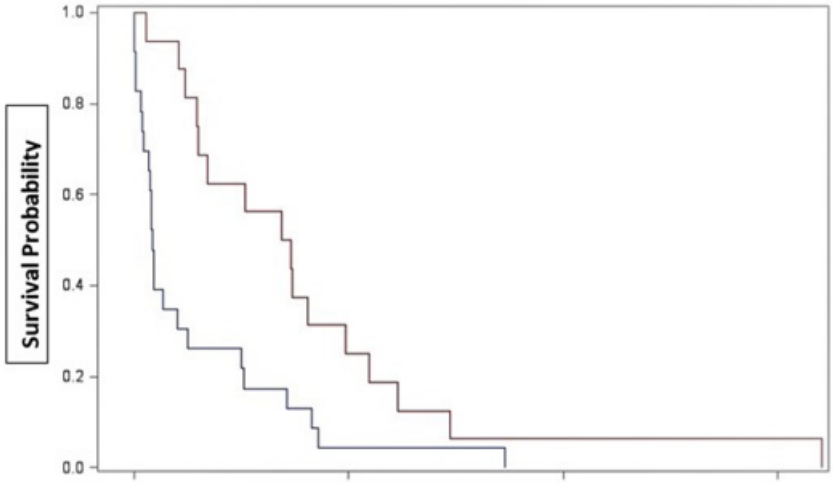


Figure 2: Total serum bilirubin level (mg/dl) before (p =0.1487), 3 (p= 0.3204) and 7 (p = 0.7090) days after one-stage PTBS (blue) or two-stage PTBS (red) with no significant differences (T-test).



Days	0	250	500	750	1000	1250	1500
primary	23	6	1	1	0	0	0
secondary	16	10	4	1	1	1	1

Figure 3: Overall survival probability after one-stage PTBS (blue) or two-stage PTBS (red) shown by Kaplan–Meier curves. Difference was significant: p = 0.0065 (Log rank-test).

Table 2: Summarized patient and PTBS characteristics

	One-stage PTBS n= 23	Two-stage PTBS n = 16
Age in years: mean	71,9 (52-87)	76,8 (56-92)
Female	11/23	9/16
Cause of malignant bile duct obstruction		
- pancreatic cancer	13	9
- cholangiocarcinoma	4	5
- duodenal carcinoma	2	0
- papilla carcinoma	2	1
- metastasis of another carcinoma	2	1
Localization of extrahepatic bile duct obstruction		
- distal	18	11
- proximal	5	5
Cause of failed/impossible ERCP		
- gastric/duodenal outlet obstruction	12	2
- failed cannulation	2	7
- biliodigestive anastomosis	4	2
- status after gastrectomy	3	2
- complex hilar cholangiocarcinoma	1	3
Number of patients with PTBS	23	16
Number of PTBDs overall	24	42
Kind of drainage before PTBS		
- external	0	5
- internal/external	0	21
Liver side for bile duct access		
- right	5	8
- left	18	8
Guidance for bile duct access		
- fluoroscopic	0	6
- ultrasound	23	10
Endoscopic visual control of stent release		
- yes	17	10
- no	6	6

Table 3: All AEs in association with one-stage PTBS (blue) or two-stage PTBS (red) in the interval of 30 days. Classification according to the four-level ASGE AE severity grading system.

Mild AE (1)	Moderate AE (2)	Severe AE (3)	Fatal AE/death 30 days (4)
small volume biliary leak along drainage catheter, resolved spontaneously	biliary effusion, drained, prolonged stay in hospital: 4 days		
postinterventional left-sided lung embolism, prolonged stay in hospital: 3 days			
small intrahepatic hematoma, prolonged stay in hospital: 3 days			
new onset-cholangitis, prolonged stay in hospital: 3 nights	1 night in ICU due to respiratory insufficiency		migrated first metal stent, second stent inserted, ICU 1 night, cholangial sepsis, died 2 days later (possible association)
biliary effusion, drained, prolonged stay in hospital: 3 nights	biliary ascites, drained, prolonged stay in hospital: 7 days		resuscitation during intervention, died in ICU (probable association)
pneumoperitoneum, resolved spontaneously, prolonged stay in hospital: 3 days	intrahepatic hematoma, resolved spontaneously, 1 night in ICU	incomplete stent release, plastic stent additionally inserted, prolonged stay in hospital: > 10 days	died 2 days after intervention (possible association)

6. Discussion

PBIs can be associated with different AEs, ranging from harmless and self-limiting to fatal. Therefore, it is reasonable to differentiate these AEs to document precise patient harm and to make studies comparable. The ASGE recommended an AE severity grading system [13] that was applied for the first time on PTBS in this study. The results showed a similar frequency of AEs in one-stage and two-stage PTBS but significantly fewer severe AEs in two-stage PTBDs. An explanation for these findings could be that one-stage PTBS as a one-step procedure is complex and might take much time, especially if the three modalities of procedure guidance, such as ultrasound, fluoroscopy, and endoscopy, are combined in one session [8, 14]. Therefore, it might be better to perform the complete procedure in two steps, as in complex surgical procedures or complex EUS-BD [15]. Second, the primary drainage of the accumulated bile fluid in the obstructed bile duct systems supports normalization of liver function and therefore improves blood coagulation, which might be useful before the transhepatic catheter is removed. Third, there might be some delay in stent deployment, which probably facilitates biliary leak through the transhepatic access route. One-stage PTBS offers the advantage that no external or internal/external plastic catheter remains in the patient, as external transhepatic biliary catheters have a substantial risk of dislocation [16], and right-sided intercostal catheters can cause substantial discomfort and pain [17]. However, these drawbacks could be avoided in this study, as predominantly left-sided bile duct access was chosen (24 vs. 13), and mostly internal/external plastic catheters were inserted (21 vs. 5). A further method to prevent adverse events such as bleeding or biliary leak might be preventive liver tract embolization after removal of the percutaneous transhepatic catheter [18]. However, this technique was not applied in this retrospective study.

There are only two studies that have compared one-stage PTBS with two-stage PTBS. Inal et al. [7] investigated one-stage PTBS (n=44) and two-stage PTBS (n=82) in terms of stent patency and overall survival but could not find a significant difference between the two groups. The AE rate was 29.2%, and the authors postulated that 30-day AEs occurred more often in patients with two-stage PTBS. However, neither the precise number of AEs in each group was given nor the severity of AEs was weighted. Li et al. [19] did not find a significant difference between one-stage (n=108) and two-stage (n=51) PTBS in terms of clinical success, 30-day AEs or overall survival in 159 patients with malignant hilar bile duct obstruction. The authors recommended that patients with preprocedural cholangitis should receive a two-stage PTBS, but the study did not show the superiority of two-stage PTBS over one-stage PTBS in terms of preventing new onset cholangitis. Cholangitis is often reported as a procedure-related AE in PBI [20]. This study found only one case of new-onset cholangitis after PTBS. This might be due to the strict definition of procedure-related cholangitis in this study. Only cholangitis that required a change in antibiotic therapy or required prolonged antibiotic ther-

apy after intervention was defined as procedure-related cholangitis. A precise definition of cholangitis is sometimes difficult in PBI, as cholangitis might already be present before PBI, new-onset cholangitis after PBI can be masked by preprocedural antibiotic therapy, and a postprocedural increase in serum inflammatory parameters such as C-reactive protein or white blood cells might not be specific for cholangitis. Pain is often found as a minor complication in PBI and reached 14.3% in the British Biliary Drainage and Stenting Registry [21]. We did not find clinically relevant events of pain after PBIs. The reason for this might be that all patients received petidine during the procedure when dilation of the transhepatic tract was performed, which might be the most painful part of the procedure. Many of the tumor patients already received analgesics so that the procedure-related new onset pain might have been masked. Furthermore, pain was not routinely assessed before *and* after PBI by, for example, a visual analog scale, so there might be a reporting bias in terms of procedure-related pain in this study. In general, AE severity grading was not applied to pain in previous studies on PTBS, although pain probably rarely reaches an AE severity grade of severe or fatal/death according to the ASGE AE severity definitions.

This study used the ASGE AE severity grading system [13]. However, there are other AE severity grading systems, such as the AE Severity Scale of the Society of Interventional Radiology (SIR) [22], which is similar to the ASGE AE severity grading system but distinguishes 5 different AE severity grades (fatal and death have separated grades). Unfortunately, the current guidelines of the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) 2021 do not consider an AE severity grading system [3], even though PBIs might have one of the highest intervention-associated AE rates compared with surgical procedures [21]. Despite the slight differences from the SIR AE severity grading system, we believe that the four levels of the ASGE AE severity grading systems are sufficient to assess the AE differences. Overall survival probability differed significantly between one-stage PTBS (140 ± 43 days) and two-stage PTBS (403 ± 95 days). However, this difference should not be overestimated, as overall survival is substantially confounded by the underlying tumor disease, the respective medical oncological therapy, and individual personal factors such as comorbidities. Accordingly, the reported mean survival time differed substantially in other studies and reached 142 ± 134 days in one study (n= 76), which mainly included hilar cholangiocarcinoma [23], up to 360 ± 62 days in one study (n = 40), which included proximal and distal malignant extrahepatic bile duct obstruction [24].

This study is not without limitations. This study is retrospective in nature and has a small sample size. As failed papilla cannulation by ERCP is very uncommon in this center (< 3%) and the papilla can be reached by ERCP even in an altered anatomy [25], PTBS is rarely necessary. Therefore, a prospective multicenter study is warranted to clarify whether one-stage or two-stage PTBS is better in terms of associated AEs. Furthermore, procedure-associated pain might have been underreported in this study, as patient-reported pain was not routinely documented in patient files.

In conclusion, this is the first time that an international four-level AE severity grading system was applied to PTBS. Two-stage PTBS was associated with fewer severe AEs than one-stage PTBS. Future studies on PTBS or EUS-guided biliary stenting might use an AE severity grading system to better compare their results in terms of AEs.

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