Bile leakage after hepatobiliary and pancreatic surgery: A definition and grading of severity by the International Study Group of Liver Surgery

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Background. *Despite the potentially severe impact of bile leakage on patients' perioperative and long-term outcome, a commonly used definition of this complication after hepatobiliary and pancreatic operations has not yet been established. The aim of the present article is to propose a uniform definition and severity grading of bile leakage after hepatobiliary and pancreatic operative therapy.*
Methods. *An international study group of hepatobiliary and pancreatic surgeons was convened. A consensus definition of bile leakage after hepatobiliary and pancreatic operative therapy was developed based on the postoperative course of bilirubin concentrations in patients' serum and drain fluid.*
Results. *After evaluation of the postoperative course of bilirubin levels in the drain fluid of patients who underwent hepatobiliary and pancreatic operations, bile leakage was defined as bilirubin concentration in the drain fluid at least 3 times the serum bilirubin concentration on or after postoperative day 3 or as the need for radiologic or operative intervention resulting from biliary collections or bile peritonitis. Using this criterion severity of bile leakage was classified according to its impact on patients' clinical management. Grade A bile leakage causes no change in patients' clinical management. A Grade B bile leakage requires active therapeutic intervention but is manageable without relaparotomy, whereas in Grade C, bile leakage relaparotomy is required.*
Conclusion. *We propose a simple definition and severity grading of bile leakage after hepatobiliary and pancreatic operative therapy. The application of the present proposal will enable a standardized comparison of the results of different clinical trials and may facilitate an objective evaluation of diagnostic and therapeutic modalities in the field of hepatobiliary and pancreatic operative therapy. (Surgery 2011;149:680-8.)*

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Surgical resection is the primary therapy for various hepatobiliary diseases.[1] Advances in surgical technique and perioperative management have decreased the morbidity and mortality substantially after hepatobiliary and pancreatic operations over recent decades.[2,3] Bile leakage, however, remains a major cause of postoperative morbidity, often leading to a prolonged hospital stay, delayed removal of abdominal drains, and need for additional (invasive) diagnostic tests and interventions, respectively.[4] In severe cases, bile leakage causes abdominal sepsis and may result in death. Besides its impact on perioperative outcome, the development of bile leakage as a surgical complication may affect the long-term outcome of patients adversely undergoing operative treatment for malignant disease.[5-8]

Bile leakage can develop after a broad range of surgical interventions of the liver, gallbladder, and bile ducts. In this context, one must differentiate between bile leakage from the cut surface of the liver after liver resection without biliary reconstruction and bile leakage after biliary reconstruction (ie, hepaticoenterostomy) in hepatobiliary interventions including those of the pancreatic head. Despite its known relevance for the outcome of patients undergoing hepatobiliary and pancreatic operative therapy, no standardized definition and grading of bile leakage currently exists. This lack of standardization, in part, may explain why the proportion of patients found to have this complication varies considerably across surgical reports. The incidence of bile leakage after liver resection without biliary reconstruction ranges from 3.6% to 12%[9] and after hepaticojejunostomy ranges from 0.4% to 8%.[10] Owing to the various applied definitions, an accurate comparison of results from different studies and institutions has not yet been possible. Recently, definitions of 3 major complications after pancreatic and rectal operative therapy have been published in an attempt to standardize reporting within clinical studies.[11-14] Although these definitions have gained rapid wide acceptance, a standardized definition and grading of severity has not yet been established for bile leakage after hepatobiliary and pancreatic operations. For this reason, our aim was to suggest a generally applicable definition of bile leakage that may be used in reports of patients undergoing hepatobiliary and pancreatic operations.

METHODS

Literature search. An extensive search of the literature was performed within the Medline database. To identify existing definitions of bile leakage, we reviewed articles on hepatobiliary operations and pancreatic head resections of the past 20 years. Furthermore, we screened studies on liver and pancreatic head resections published in the leading surgery journals within the past 5 years to determine whether a definition of bile leakage has been accepted already among hepatobiliary surgeons. No restrictions were in place in regard to the indication for liver and pancreatic operative therapy (ie, malignant or benign disease) or the surgical techniques applied (eg, transection of the liver parenchyma).

Patients. Patients who underwent hepatic resection ($n = 50$) or pancreatic resection ($n = 25$) with an uneventful postoperative course at the Departments of General, Visceral, and Transplantation Surgery, University of Heidelberg were included in an analysis to evaluate the postoperative changes of bilirubin concentrations in the serum and drain fluid. Patients were treated as described previously.[15-17] The proposed definition and classification of severity was applied subsequently in separate validation cohorts of patients who underwent hepatic resection ($n = 70$) or pancreatic resection ($n = 50$) at the same institution.

Study group. An international study group of liver surgery (ISGLS) was convened in August 2008. Drafts of the definition and severity grading of bile leakage after hepatobiliary and pancreatic operations were sent to the members of the ISGLS for critical review.

During the Annual Meeting of the Australian and New Zealand Hepatic, Pancreatic and Biliary Association in Coolum, Australia in October 2008, a consensus conference was held. The proposal was discussed extensively at this meeting, and the decision was made to consider the actual postoperative course of bilirubin concentrations in the serum and drain fluid of patients undergoing hepatic and pancreatic resection for the definition

of bile leakage. After data collection was completed, a revised version of the manuscript was sent to the members of the ISGLS in February 2010. In March 2010, the manuscript was recirculated among the authors for final approval.

Statistical analyses. Categorical variables were presented as absolute and relative frequencies. Continuous variables were expressed as median and range and were compared using the Mann-Whitney *U* test. Statistical analyses were carried out using JMP software (SAS Institute, Cary, NC).

RESULTS

Terminology. The terms "bile leakage," "bile leak," "biliary fistula," "biliary leakage," and "biliary leak" were used in the literature to report postoperative loss of bile fluid via abdominal drains after hepatobiliary and pancreatic operative therapy. The term "bilioma" was used primarily for postoperative bile fluid collection in the abdominal cavity requiring drainage.

Available definitions in the literature. Our review of the literature revealed that a generally used or accepted definition of bile leakage has not been established. Many different definitions have been used in the various studies on hepatic and pancreatic operative therapy. In most cases, the definition of postoperative bile leakage was based on rather arbitrary cut-off values for the volume of drain fluid and/or the bilirubin concentration within the drain fluid. These cut-off values varied and ranged from 20 to 50 mL for the volume of drain fluid[10,18-20] and from 5 to 20 mg/dL for the concentration of bilirubin in the drain fluid.[21-23] Furthermore, some authors related the bilirubin concentration in the drain fluid to the serum bilirubin concentration to make the diagnosis of bile leakage.[24-26] Most definitions of bile leakage included certain time points or time intervals that varied between 24 hours and 14 days after operation.[10,18,20-22,27] Finally, an abdominal collection of bile fluid that was detected either by percutaneous drainage or during re-operation also was defined as bile leakage by some authors.[9,25,28]

Few studies described a grading system to report the severity of bile leakage. One study used a grading system based exclusively on specific radiologic examinations and, therefore, was not applicable for the routine clinical setting.[26] Another study distinguished between minor and major bile leakage, but this classification was designed only for the purpose of their specific analysis.[28] Bruce et al suggested a grading system of 3 grades of hepatopancreaticobiliary leakage based on the patient's symptoms and the management required. These authors distinguished a radiologic leak with no clinical symptoms and no change in management, a minor leak with >50 mL drainage per day requiring no change in management, and a major leak with severe disruption of the anastomosis requiring a change in patients' management.[29]

Consensus definition of bile leakage after hepatobiliary and pancreatic operative therapy. The postoperative changes in bilirubin concentrations in the drain fluid and serum were analyzed in patients who underwent hepatic resection ($n = 50$) or pancreatic head resection and total pancreatectomy ($n = 25$) with an uneventful postoperative course (Table I). These analyses showed that postoperative bilirubin concentrations in the drain fluid and serum were similar in patients with hepatic resection (Fig, *A*) and pancreatic resection (Fig, *B*).

Considering the regular kinetics of bilirubin concentrations in the drain fluid and serum, we suggest defining bile leakage after hepatobiliary and pancreatic resection as a discharge of fluid with an increased bilirubin concentration via the intra-abdominal drains on or after postoperative day 3 *or* as the need for radiologic intervention (ie, interventional drainage) and relaparatomy for biliary collections and bile peritonitis, respectively. Increased bilirubin concentration in the intra-abdominal drain or within biliary collections are defined as a bilirubin concentration at least 3 times the serum bilirubin concentration measured at the same time.

Bile leakage may originate from the cut surface of the liver, from injury of the bile ducts, or from anastomotic leakage after bilioenteric anastomosis.

Grading of bile leakage. The presented consensus definition should be applied to identify the postoperative complication of bile leakage. This definition includes all clinical presentations of postoperative bile leakage ranging from asymptomatic bile leakage to life-threatening conditions. To provide a classification of the severity of bile leakage, we propose a grading system that stages bile leakage into 3 grades (A–C) based on the impact of this complication on patients' clinical management (Table II).

Bile leakage grade A: Grade A bile leakage has little or no impact on patients' clinical management. These patients remain in a good clinical condition, and leakage is controlled adequately by an intra-abdominal drain. The volume of drain fluid usually decreases daily as does the bilirubin concentration of the fluid. Additional diagnostic or therapeutic interventions are not necessary. Abdominal imaging, however, may demonstrate

Table I. Clinicopathologic data of patients with an uneventful postoperative course*

Hepatic resection (n = *50*)		*Pancreatic resection* (n = *25*)	
Age [years]	62 (37–82)	Age [years]	61 (37–83)
Sex		Sex	
Male	22 (44)	Male	16 (64)
Female	28 (56)	Female	9 (36)
Diagnosis		Diagnosis	
Primary malignancy	12 (24)	Pancreatic cancer	11 (44)
Metastatic disease	34 (68)	Chronic pancreatitis	8 (32)
Benign disease	4 (8)	Other	6 (24)
Surgical procedure		Surgical procedure	
Right hemihepatecomy	13 (26)	Pancreatico-duodenectomy	20 (80)
Left hemihepatectomy	7 (14)	Total pancreatectomy	2 (8)
Other anatomic resection	15 (30)	DPPHR	3 (12)
Atypical resection	15 (30)		
Bilirubin (serum)		Bilirubin (Serum)	
Pre OP [mg/dL]	0.5 (0.2–8.9)	Pre OP [mg/dL]	0.7 (0.3–16.7)
POD 1 [mg/dL]	1.0 (0.2–4.7)	POD 1 [mg/dL]	0.8 (0.4–8.9)
POD 2 [mg/dL]	0.8 (0.2–5.6)	POD 2 [mg/dL]	0.5 (0.2–6.6)
POD 3 [mg/dL]	0.7 (0.2–5.0)	POD 3 [mg/dL]	0.4 (0.2–7.3)
POD 4 [mg/dL]	0.6 (0.2–4.6)	POD 4 [mg/dL]	0.5 (0.2–6.4)
POD 5 [mg/dL]	0.5 (0.2–4.9)	POD 5 [mg/dL]	0.6 (0.2–5.0)
Bilirubin (Drain)		Bilirubin (Drain)	
POD 1 [mg/dL]	0.7 (0.2–15.4)	POD 1 [mg/dL]	1.0 (0.3–8.3)
POD 2 [mg/dL]	0.8 (0.1–9.2)	POD 2 [mg/dL]	0.5 (0.1–7.1)
POD 3 [mg/dL]	0.7 (0.1–3.6)	POD 3 [mg/dL]	0.5 (0.1–5.5)
POD 4 [mg/dL]	0.7 (0.1–4.0)	POD 4 [mg/dL]	0.7 (0.1–5.4)
POD 5 [mg/dL]	0.7 (0.1–4.0)	POD 5 [mg/dL]	0.6 (0.2–5.8)

*Data are presented as absolute numbers (percentage) or median (range).
DPPHR, Duodenum-preserving pancreatic head resection; *POD*, postoperative day.

perihepatic fluid collections that are not associated with clinical symptoms. Prolonged drainage via the intra-abdominal drains (≤1 week) may be required and hereby cause a prolonged hospital stay. A Grade A bile leakage requiring drainage for more than 1 week should be classified as Grade B bile leakage (see subsequent section).

Bile leakage grade B: A bile leakage requiring a change in patients' clinical management but can be treated without relaparotomy is defined as Grade B. The clinical condition of the patient is compromised moderately, and these patients often present with parameters suggestive of infection, such as fever and/or abdominal discomfort. Although the operatively placed drains are commonly left in place, these drains may not entirely drain the leakage. Additional imaging studies are performed often in these patients and typically demonstrate an intra-abdominal fluid collection and anastomotic leakage (if a bilioenteric anastomosis was performed), respectively. Although most patients with Grade B bile leakage may require antibiotic therapy, subsequent radiologic and endoscopic procedures are often indicated. Besides percutaneous intra-abdominal drainage of fluid collections, additional invasive therapy may include endoscopic retrograde cholangiography with placement of an intrahepatic stent and percutaneous transhepatic cholangiodrainage to control bile leakage from the cut surface or a bile duct injury and bilioenteric anastomosis, respectively. Patients' postoperative hospital stay is prolonged, and some patients may be discharged with drains in situ to be treated in the outpatient setting. A Grade A bile leakage requiring drainage for more than 1 week also should be classified as Grade B bile leakage.

Bile leakage grade C: Patients with a Grade C bile leakage require relaparotomy to control this complication. Operative procedures include manuevers such as suture closure of leaking bile ducts, clearance of intra-abdominal fluid collections, and (re-)construction of a bilioenteric anastomosis. Furthermore, additional drains for continuous postoperative lavage may be placed. These patients may present in a life-threatening condition with

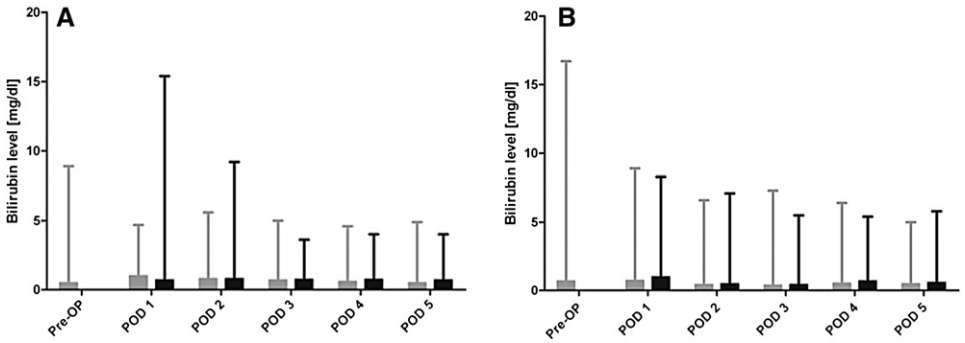

Fig. Perioperative bilirubin concentrations in the serum and drain fluid of patients after (*A*) hepatic resection and (*B*) pancreatic resection requiring pancreatoenterostomy. *Grey bars* indicate serum bilirubin levels. *Black bars* indicate bilirubin levels in the drain fluid. Data are presented as median and upper range. Bilirubin levels are presented as mg/dL.

Table II. Consensus proposal of the ISGLS for a definition and grading of bile leakage after hepatobiliary and pancreatic surgery

Definition	Bile leakage is defined as fluid with an increased bilirubin concentration in the abdominal drain or in the intra-abdominal fluid on or after postoperative day 3, or as the need for radiologic intervention (ie, interventional drainage) because of biliary collections or relaparotomy resulting from bile peritonitis.
	Increased bilirubin concentration in the drain or intra-abdominal fluid is defined as a bilirubin concentration at least 3 times greater than the serum bilirubin concentration measured at the same time.
Grade	
A	Bile leakage requiring no or little change in patients' clinical management
B	Bile leakage requiring a change in patients clinical management (eg, additional diagnostic or interventional procedures) but manageable without relaparotomy, *or* a Grade A bile leakage lasting for >1 week
C	Bile leakage requiring relaparotomy

severe abdominal pain or bile peritonitis. Their clinical condition might be complicated by single or multiorgan failure. These patients often require treatment in a critical care facility. Radiologic imaging is performed and usually shows signs of either an intra-abdominal fluid collection or an anastomotic leakage (in case of hepaticoenterostomy). Radiologic and/or endoscopic interventions may have been performed already in patients with Grade C bile leakage. The postoperative course of the patients is prolonged, and secondary postoperative complications (eg, abdominal wound infection) may result.

Early postoperative bile leakage after hepaticoenterostomy (without previous radiologic imaging or intervention) may represent a special indication for immediate operative intervention and reconstruction of the bilioenteric anastomosis. Even though the clinical condition of these patients might be less severe, they also should be classified as having Grade C bile leakage because of the invasiveness of required therapy.

The common clinical characteristics of patients with bile leakage and the main parameters for grading bile leakage are presented in Table III.

Validation of the definition and grading of bile leakage after hepatic and pancreatic resection. The proposed definition of bile leakage together with the grading of severity were applied to a consecutive series of patients who underwent hepatic resection (n = 70) and pancreatic resection (n = 50) to assess its applicability and for the purpose of validation (Table IV). In patients with hepatic resection, bile leakage was found in 11 (16%) patients, whereas Grades A, B, and C bile leakage were present in 4 (6%), 6 (9%), and 1 (1%) patients, respectively. The hospital stay of patients with Grade B bile leakage (20; 16–26 days) was prolonged compared with patients with Grade A leakage (9.5; 7.5–14.5 days) (P = .03). In patients with pancreatic resection, bile leakage occurred in 5 (10%) patients. The severity of bile leakage in these patients was classified as Grade

Table III. Common clinical characteristics of patients and main parameters for grading of bile leakage

	Grade A	*Grade B*	*Grade C*
Clinical condition	Mildly impaired	Moderately impaired	Severely impaired
Clinical symptoms	Commonly no	May have abdominal pain and/or signs of infection	Life-threatening condition with possible single or multi-organ failure and/or biliary peritonitis
Persistent drainage (>1 week)	No	Commonly yes	Yes
Need for diagnostic assessment	No	Commonly yes	Yes
Radiologic imaging positive (eg, bilioma, abscess, or leakage)	Possibly yes	Commonly yes	Commonly yes
Radiologic or endoscopic intervention	No	Commonly yes*	No/Yes
Relaparotomy	No	No	Yes
Prolonged hospital stay	Commonly no	Commonly yes	Yes

*Patients with a Grade A bile leakage persisting for >1 week are diagnosed with Grade B leakage regardless of the need for therapeutic intervention.

Table IV. Clinicopathologic data of the validation cohorts*

Hepatic resection (n = 70)		*Pancreatic resection (n = 50)*	
Age [years]	58 (28–81)	Age [years]	62 (42–85)
Sex		Sex	
Male	41 (59)	Male	32 (64)
Female	29 (41)	Female	18 (36)
Diagnosis		Diagnosis	
Primary malignancy	16 (23)	Pancreatic cancer	20 (40)
Metastatic disease	42 (60)	CCC	5 (10)
Benign disease	12 (17)	Chronic pancreatitis	9 (18)
		Other	16 (32)
Surgical procedure		Surgical procedure	
Right hemihepatecomy	17 (23)	Pancreatico-duodenectomy	35 (70)
Left hemihepatectomy	17 (23)	Total pancreatectomy	11 (22)
Other anatomic resection	22 (32)	DPPHR	4 (8)
Atypical resection	16 (22)		
Hospital stay [days]	11 (6–76)	Hospital stay [days]	14 (9–69)
Bile leakage severity	11 (16)	Bile leakage severity	5 (10)
Grade A	4 (6)	Grade A	2 (4)
Grade B	6 (9)	Grade B	2 (4)
Grade C	1 (1)	Grade C	1 (2)

*Data are presented as absolute numbers (percentage) or median (range).
CCC, Cholangio cellular carcinoma.

A, B, and C in 2 (4%), 2 (4%), and 1 (2%) patients, respectively.

To determine whether the applied threshold to define bile leakage was appropriate and clinically meaningful, we performed additional exploratory analyses using lesser and greater cut-off values ("2-times" and "4-times" the serum bilirubin concentration) for the diagnosis of bile leakage.

The lesser threshold ("2-times") resulted in an increased number of patients with bile leakage after hepatic resection (n = 14, 20%), which was caused by more patients graded as Grade A bile leakage (n = 7, 10%), whereas no difference was noted in the number of patients with Grade B and C bile leakage. This effect was more pronounced after pancreatic resections in which 19 (38%) patients would have developed a bile leakage. A total of 16 (32%) of these patients had Grade A bile leakage if the diagnosis was based on the lesser threshold ("2-times").

Bilirubin concentrations in the drain fluid 4 times the serum bilirubin concentration revealed results that were identical to the 3-times cut-off with respect to the number of patients with bile leakage and those with the various grades of severity.

DISCUSSION

Bile leakage may develop after a broad range of operative interventions of the gallbladder, bile ducts, and liver. Despite improvements in operative technique and perioperative care in the field of hepatic and pancreatic operative therapy, bile leakage remains a major source of concern because of its potential impact on patients' outcome. The clinical presentation of bile leakage varies from asymptomatic drainage of biliary fluid to life-threatening conditions such as biliary sepsis and massive hemorrhage. Furthermore, accumulating evidence suggests that surgical complications impair long-term prognosis of patients undergoing a hepatobiliary operation for malignant disease.[5-8] The impact of bile leakage on the outcome of patients undergoing hepatobiliary and pancreatic operations may explain why this complication is used frequently to evaluate operative interventions. Because valid comparison of the results from different techniques and studies requires standardized definition of outcomes, an increasing interest has been developing among gastrointestinal surgeons to generate uniform definitions and grading of the severity of postoperative outcome parameters after various operative procedures. For pancreatic operations, uniform definitions of the most relevant complications, such as postoperative pancreatic fistula, postpancreatectomy hemorrhage, and delayed gastric emptying, already have been formulated and accepted internationally.[11-13] Our literature search, however, revealed that a uniform definition of bile leakage after hepatobiliary and pancreatic operative therapy has not yet been established. This finding is in accordance with a systematic review published in 2001 that demonstrated a lack of universally accepted definitions of anastomotic leak after various kinds of gastrointestinal operations.[29]

Most definitions identified by our literature search applied various cut-off levels of bilirubin concentration in the drain fluid to define the presence of bile leakage. These cut-off values, however, were chosen arbitrarily. For the purpose of the present definition, we considered the postoperative changes of bilirubin concentrations in the serum and drain fluid of patients undergoing hepatic and pancreatic resection who had an uneventful postoperative course. The bilirubin concentrations in the drain fluid and serum to be used for the diagnosis of bile leakage is subject of ongoing discussion among hepatobiliary and pancreatic surgeons. This finding may in part be explained by the limited number of studies assessing bilirubin concentrations in the drain fluid.

Considering the natural postoperative course of bilirubin concentrations in the serum and drain fluid, we suggest defining bile leakage after hepatobiliary and pancreatic resection as discharge of fluid with a bilirubin concentration at least 3 times greater than the serum bilirubin concentration via the intra-abdominal drains on or after postoperative day 3. Regardless of the initial bilirubin concentration via the operatively placed drains, the need for radiologic (ie, interventional drainage) or operative intervention (ie, relaparatomy) for biliary collections or biliary peritonitis also defines the diagnosis of bile leakage.

Although most identified studies defined bile leakage using cut-off levels for bilirubin concentrations in the drain fluid, several studies suggested the volume of drain fluid to identify bile leakage. We decided deliberately not to include the volume of drain fluid in our definition of bile leakage because it may be confounded by ascites or lymphatic fistula. We are well aware that these factors also may affect the concentration of bilirubin in the drain fluid. Because of the low bilirubin levels in the drain fluid of patients with an uneventful postoperative course, we are, however, confident that definition of bile leakage using the bilirubin concentration still may be applicable irrespective of the amount of concomitant ascites. Because intraoperative drains usually are placed in the operative field near the site of hepatic transection or in close proximity to a bilioenteric anastomosis, concomitant ascites is unlikely to change bilirubin concentrations in the drain fluid substantially.

The severity of bile leakage (ie, its impact on patients' well-being) may vary considerably. Our literature search revealed that only few studies graded the severity of this complication to provide a more accurate picture of patients' clinical condition. In addition to criteria needed for the diagnosis of bile leakage, classification of severity is required to evaluate and compare the results from different studies. In accordance with the clinical grading system proposed by Bruce et al, we suggest grading the severity of bile leakage based on the impact on patients' clinical management. Although asymptomatic bile leakage resulting in no change in patients' clinical pathway represents a Grade A bile leakage, bile leakage that requires therapeutic

intervention but can be managed with and without relaparotomy should be considered Grade B and Grade C, respectively. Our Grade A and C bile leakage may be comparable with the "radiologic leak" and "clinical major leak" proposed by Bruce et al,[29] whereas our Grade B leakage differs from what these authors label a "clinical minor leak." Despite the presence of clinical symptoms such as fever and increased white blood cell count, these authors did not consider a change in patients' clinical management. As suggested for our Grade B leakage, we are convinced that these patients usually undergo subsequent diagnostic procedures and are treated frequently with antibiotics and interventional drainage, respectively. It also should be noted that chronic use of antibiotics does not change the grade of bile leakage from Grade B to Grade C unless a relaparotomy is required. Moreover, no evidence has been found to support the use of chronic antibiotic therapy in patients with bile leakage. In another study, bile leakage was divided into 4 groups based on the results of postoperative fistulograms.[26] Most institutions do not perform routine radiologic imaging and/or fistulography in all patients with suspected bile leakage; therefore, this classification may not be as useful in all patients. We also did not classify bile leakage based on the location of leakage (eg, liver surface or bile duct) as suggested by other authors,[28] because the severity of leakage is usually not determined by its origin. Furthermore, the bilirubin concentration in the drain fluid does not necessarily reflect patients' clinical condition and therefore was not considered in our grading of severity, although it is important for making the actual diagnosis of bile leakage. Any application of the present grading of severity requires accurate reporting with respect to the numbers of patients who received an abdominal drain.

In conclusion, we suggest a definition and grading of severity to standardize reporting of bile leakage after hepatobiliary and pancreatic operative therapy. The proposal was developed based on objective patient data to ensure external validity. This classification, however, requires prospective validation, as has been carried out for the definition and severity grading of postoperative pancreatic fistula.[30] One should note that application of this proposed definition as well as grading of severity relies on commonly acquired data during routine management of patients undergoing an operation for hepatobiliary or pancreatic diseases. The present proposal complies with previous classifications of surgical complications[11-14,31] and is easily applicable in clinical practice. Use of this classification should allow comparison of results from future clinical studies and should enable the medical and surgical community to assess the outcomes of studies better and to evaluate novel treatments.

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