Diagnosis and management of bile leaks after severe liver injury: A Trauma Association of Canada multicenter study

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BACKGROUND: Optimal management of bile leaks (BLs) after severe liver injury is unknown. Study objectives were to define current practices in diagnosis and management of BL to determine which patients may benefit from endoscopic retrograde cholangiopancreatography (ERCP).

METHODS: American Association for the Surgery of Trauma grade ≥III liver injuries from 10 North American trauma centers were included in this retrospective study (February 2011 to January 2021). Groups were defined as patients who developed BL versus those who did not. Subgroup analysis of BL patients was performed by management strategy. Bivariate analysis compared demographics, clinical/injury data, and outcomes. Receiver operating characteristic curves were performed to investigate the relationship between bilious drain output and ERCP.

RESULTS: A total of 2,225 patients with severe liver injury met the study criteria, with 108 BLs (5%). Bile leak patients had higher American Association for the Surgery of Trauma grade of liver injury ($p < 0.001$) and were more likely to have been managed operatively from the outset (69% vs. 25%, $p < 0.001$). Bile leak was typically diagnosed on hospital day 6 [4–10] via surgical drain output (n = 37 [39%]) and computed tomography scan (n = 34 [36%]). On the BL diagnosis day, drain output was 270 [125–555] mL. Endoscopic retrograde cholangiopancreatography was the most frequent management strategy (n = 59 [55%]), although 32 patients (30%) were managed with external drains alone. Bile leak patients who underwent ERCP, surgery, or percutaneous transhepatic biliary drain had higher drain output than BL patients who were managed with external drains alone (320 [180–720] vs. 138 [85–330] mL, $p = 0.010$). Receiver operating characteristic curve analysis of BL demonstrated moderate accuracy (area under the receiver operating characteristic curve, 0.636) for ERCP at a cutoff point of 390 mL of bilious output on the day of diagnosis.

CONCLUSION: Patients with BL >300 to 400 mL were most likely to undergo ERCP, percutaneous transhepatic biliary drain, or surgical management. Once external drainage of BL has been established, we recommend ERCP be reserved for patients with BL >300 mL of daily output. Prospective multicenter examination will be required to validate these retrospective data. (*J Trauma Acute Care Surg.* 2022;93: 813–820. Copyright © 2022 Wolters Kluwer Health, Inc. All rights reserved.)

LEVEL OF EVIDENCE: Therapeutic and Care Management; Level IV.

KEY WORDS: Severe liver injury; bile leak; complication; trauma; endoscopic retrograde cholangiopancreatography.

Severe hepatic injury occurs after both blunt and penetrating trauma. Because of the extent and severity of these liver injuries, numerous complications can occur,[1] including pseudoaneurysms, hepatic necrosis, hemobilia,[2] and bile leaks.[3,4] The nuances of bile leak diagnosis and management are not yet empirically defined. Part of the challenge in the evidence-based management of traumatic bile leaks is the paucity of data to guide treatment, with the vast majority of bile leaks occurring following cholecystectomy.[5,6] Therefore, the need for and timing of interventions for traumatic bile leak management and the utility of various investigations used to confirm the diagnosis of bile leak are not yet established by existing literature. Internal biliary drainage via endoscopic retrograde cholangiopancreatography (ERCP) with sphincterotomy and/or biliary stenting is the mainstay of bile leak management, with success rates that approach 100% and relatively low rates of complications.[3,5,7,8] Literature exists, however, that many bile leaks may be treated successfully without internal biliary drainage, that is, with observation ± percutaneous drainage alone.[9–11] Delineation of the optimal management of patients with bile leaks following severe liver injury is of critical interest to clinicians.

The primary objective of this study was to define the incidence, diagnosis, and management of bile leaks after severe liver trauma at trauma centers across North America. The secondary objectives were characterization of risk factors for bile leak after liver trauma and for need for ERCP for bile leak management. Our hypothesis was that bile leaks would occur often, be diagnosed principally via drain output quantity and quality, and be managed largely with ERCP.

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PATIENTS AND METHODS

In this multicenter retrospective observational study, all trauma patients presenting to 1 of 10 North American trauma centers with an American Association for the Surgery of Trauma (AAST) grade ≥III liver injury from February 1, 2011, to January 31, 2021, were included. Patients were excluded if they were younger than 16 years, transferred, pregnant, had underlying cirrhosis or a history of prior gastric bypass surgery, or had concomitant injury precluding ERCP (e.g., duodenal injuries). Institutional review board approval was obtained by the coordinating center and each participating center. The STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) guideline was used to ensure proper reporting of methods, results, and discussion (Supplemental Digital Content, Supplementary Data 1, http://links.lww.com/TA/C653).

Variables examined included patient demographics (age, sex, comorbidities), clinical data (first vital signs and Glasgow Coma Scale score in the emergency department [ED]), injury data (mechanism of injury, AAST grade of liver injury, Abbreviated Injury Scale by body region, and Injury Severity Score), bile leak data (method of diagnosis, drain output, laboratory results, culture data, interventions, timing of interventions, failure of interventions), and outcomes (in-hospital mortality, hospital

TABLE 1. Patient Demographics, Injury Data, Clinical Data, and Outcomes After Severe Liver Trauma

	Severe Liver Injury With Bile Leak (n = 108 [5%])	Severe Liver Injury Without Bile Leak (n = 2,117 [95%])	*p*
Patient demographics			
Age, y	30 [23–39]	31 [24–45]	0.188
Sex, male	92 (85%)	1,437 (68%)	<0.001
Mechanism of injury			<0.001
Blunt (n = 1,514)	59 (55%)	1,612 (76%)	
MVC	15 (25%)	765 (47%)	
AVP collisions	10 (17%)	268 (17%)	
Fall	8 (14%)	203 (12%)	
MCCs	14 (24%)	139 (9%)	
Assault	1 (1%)	43 (3%)	
Other	11 (19%)	194 (12%)	
Penetrating (n = 509)	49 (45%)	505 (24%)	
GSWs	38 (78%)	250 (50%)	
SWs	11 (22%)	203 (40%)	
Assault	0 (0%)	15 (3%)	
Other	0 (0%)	37 (7%)	
ISS	29 [20–35]	26 [18–34]	0.216
AIS			
Head and neck	0 [0–0]	0 [0–2]	<0.001
Face	0 [0–0]	0 [0–0]	0.160
Chest	3 [2–3]	3 [2–3]	0.863
Abdomen and pelvis	4 [3–4]	3 [3–4]	<0.001
Extremities	0 [0–2]	1 [0–2]	0.017
External	0 [0–0]	0 [0–1]	<0.001
AAST grade of liver injury			<0.001
III	22 (20%)	1,109 (52%)	
IV	61 (57%)	777 (37%)	
V	25 (23%)	226 (11%)	
VI	0 (0%)	5 (<1%)	
First ED vital signs			
SBP, mm Hg	116 [88–135]	121 [104–138]	0.029
SBP <90 mm Hg	28 (27%)	270 (13%)	<0.001
HR, beats per minute	102 [90–120]	93 [78–110]	<0.001
HR >120 beats per minute	25 (24%)	290 (14%)	0.004
GCS	15 [13–15]	15 [13–15]	0.935
GCS <9	9 (9%)	340 (17%)	0.039
Initial management			<0.001
NOM	22 (20%)	1,429 (67%)	
OM	74 (69%)	521 (25%)	
AE	12 (11%)	95 (5%)	
ED death	0 (0%)	5 (<1%)	
Unknown	0 (0%)	67 (3%)	
In-hospital mortality	0 (0%)	306 (15%)	<0.001
Hospital LOS	25 [15–44]	6 [3–14]	<0.001
ICU LOS	7 [3–18]	2 [0–6]	<0.001
Ventilator days	3 [0–14]	1 [0–4]	<0.001

Continuous variables are presented as median [interquartile range]. Categorical variables are presented as number (percentage).

AE, angioembolization; AIS, Abbreviated Injury Scale; AVP, auto versus pedestrian collision; GCS, Glasgow Coma Scale; GSW, gunshot wound; HR, heart rate; ISS, Injury Severity Score; MCC, motorcycle collision; MVC, motor vehicle collision; NOM, nonoperative management; OM, operative management; SBP, systolic blood pressure; SW, stab wound.

length of stay [LOS; in days], intensive care unit [ICU] LOS). Because the AAST grading system for solid organ injuries was revised in 2018, which occurred during the study period, the AAST grading system in use at the time of patient contact was utilized. Only biochemically confirmed bile leaks, in accordance with the International Study Group of Liver Surgery definition of bile leak,[12] were considered and graded as follows: A, bile leak that does not change management; B, bile leak that necessitates

TABLE 2. Bile Leak Diagnosis and Evaluation

	Patients With Bile Leak (n = 108)
Grade of bile leak*	
A	15 (14%)
B	61 (56%)
C	29 (27%)
Unknown	3 (3%)
Hospital day of diagnosis of bile leak	6 [4–10]
Methods of diagnosis	
Surgical drain output	37 (39%)
CT scan	34 (36%)
Elevated serum bilirubin	23 (21%)
Visualized during initial operations	18 (17%)
HIDA scan	13 (12%)
Percutaneous drain after CT	12 (11%)
MRCP	6 (6%)
Abdominal pain	5 (5%)
US	2 (2%)
Daily drain output on day of diagnosis,** mL	270 [125–555]
Peak serum bilirubin, mg/dL	6.7 [1.9–25.0]
Bile leak sent for culture	46 (43%)
No growth	21 (46%)
Candida/yeast	6 (13%)
Enterococcus	6 (13%)
Pseudomonas	6 (13%)
Streptococcus anginosus	4 (9%)
Enteric bacilli	2 (4%)
Prevotella denticola	2 (4%)
Serratia marcescens	2 (4%)
Staphylococcus aureus	2 (4%)
Clostridium perfringens	1 (2%)
Coagulase-negative staphylococci	1 (2%)
Enterobacter cloacae	1 (2%)
Escherichia coli	1 (2%)
Group B streptococcus	1 (2%)
Prevotella nigrescens	1 (2%)
Staphylococcus hemolyticus	1 (2%)
Staphylococcus epidermidis	1 (2%)
Streptococcus viridans	1 (2%)

*Grade of bile leak was classified as follows: A, bile leakage that does not change the patient's management; B, bile leakage that requires therapeutic intervention but does not necessitate surgery; C, bile leakage for which laparotomy is required for management.[12]

**Daily drain output on day of diagnosis, reported for patients with a surgical drain in situ at the time of diagnosis.

Continuous variables are presented as median [interquartile range]. Categorical variables are presented as number (percentage).

CT, computer tomography; HIDA, hepatobiliary iminodiacetic acid; MRCP, magnetic resonance cholangiopancreatography; US, ultrasound.

therapeutic intervention other than surgery; and C, bile leak that requires laparotomy.[12] The management of severe liver trauma and of resultant bile leaks were not protocolized at any participating institution, and therefore, investigation and management decisions were at the discretion of the attending trauma surgeon.

Study groups were defined as patients with severe liver injury with bile leak versus those without bile leak. Subgroups analysis of patients with bile leak was performed based on bile leak management strategy: intervention (defined as ERCP, surgery, or percutaneous transhepatic biliary drain [PTBD]) versus no intervention (defined as management with drains alone, either surgically placed at index operative intervention for severe liver injury or percutaneously placed to treat bile leakage). Bivariate analyses compared patient characteristics, clinical data, injury data, and outcomes between groups. Descriptive statistics summarized diagnostic tests and interventions for bile leak. Continuous variables are presented as median [interquartile range] and compared using Student's t test and Mann-Whitney U test. Categorical variables are presented as number (percentage) and compared using the χ^2 test. Multivariable analyses with logistic regression were performed to identify independent factors associated with the development of bile leak after severe liver injury and use of ERCP for bile leak management. Clinically relevant variables and those with p value <0.2 on univariable analysis were entered into the regression model. Results of the multivariable analyses are presented as odds ratios (ORs) with

TABLE 3. Bile Leak Management

	Patients With Bile Leak (n = 108)
ERCP	59 (55%)
Hospital day performed	13 [8–18]
ERCP interventions	
Stent alone	22 (37%)
Biliary stent	19 (32%)
Pancreatic duct stent	4 (7%)
Sphincterotomy alone	4 (7%)
Both stent and sphincterotomy	33 (56%)
Post ERCP pancreatitis	1 (2%)
Failure of ERCP*	15 (25%)
Repeat ERCP	8 (53%)
Percutaneous drain	5 (33%)
Surgical intervention	4 (27%)
Nonanatomic hepatic resection	1 (25%)
Exploratory laparotomy and washout	1 (25%)
Laparoscopy and washout	1 (25%)
Unspecified	1 (25%)
Time from ERCP to leak resolution, d	30 [10–52]
Drain placement alone	32 (30%)
Surgical drain**	21 (66%)
Total days in situ	16 [11–26]
Percutaneous drain	11 (34%)
Hospital day inserted	13 [10–21]
Total days in situ	15 [12–21]
Operative intervention (exploratory laparotomy)†	16 (15%)
Washout and drainage	10 (63%)
Hepatorhaphy	6 (38%)
Nonanatomic hepatic resection	5 (31%)
PTBD	1 (<1%)

Continuous variables presented as median [interquartile range]. Categorical variables presented as number (percentage).

*Defined as need for further intervention for bile leak management after performance of ERCP. Categories are not mutually exclusive.

**Managed with a surgical drain already in situ.

†Some patients underwent more than one procedure at the time of operative intervention via exploratory laparotomy.

95% confidence intervals; receiver operating characteristic curves of the relationship between drain output on day of diagnosis and use of ERCP, as well as for drain output on postdiagnosis day 3 and use of for ERCP, were performed. Statistical significance was defined as $p < 0.05$. Data were collected and analyzed using IBM SPSS Statistics 28 (IBM Corporation, Armonk, NY).

RESULTS

In total, 2,225 patients with severe liver injury met the study criteria. Of these, 2,117 patients (95%) did not develop a bile leak and 108 (5%) did (Table 1). Patients with bile leak were more likely to be injured by penetrating trauma than patients without bile leak (45% vs. 24%, $p < 0.001$). Bile leak patients had higher Abbreviated Injury Scale abdomen/pelvis scores than did patients without bile leak (4 [3–4] vs. 3 [3–4], $p < 0.001$) despite having comparable Injury Severity Score (29 [20–35] vs. 26 [18–34], $p = 0.216$). Patients with bile leak were more likely to be managed operatively from the outset (69% vs. 25%, $p < 0.001$) and had higher AAST grades of liver injury ($p < 0.001$). By AAST grade of liver injury, 2% of grade III, 7% of grade IV, and 10% of grade V injuries developed a bile leak. Hospital and ICU LOS as well as ventilator days were significantly longer among patients with than without a bile leak, although in-hospital mortality was lower ($p < 0.001$), which may reflect survival bias (Table 1).

TABLE 4. Patient Demographics, Injury Data, Clinical Data, and Diagnostic Data Among Patients With Bile Leak Managed With and Without Intervention

	Patients With Bile Leak and Intervention (n = 76 [70%])	Patients With Bile Leak and No Intervention (n = 32 [30%])	*p*
Patient demographics			
Age, y	30 [24–39]	31 [23–40]	0.960
Sex, male	65 (86%)	27 (84%)	1.000
Mechanism of injury			0.826
Blunt	41 (54%)	18 (56%)	
Penetrating	35 (46%)	14 (44%)	
ISS	29 [21–36]	27 [17–34]	0.377
AIS			
Head and neck	0 [0–0]	0 [0–0]	0.481
Face	0 [0–0]	0 [0–0]	0.875
Chest	3 [2–3]	3 [1–3]	0.850
Abdomen and pelvis	4 [4–4]	4 [3–4]	0.468
Extremities	0 [0–2]	0 [0–2]	0.784
External	0 [0–1]	0 [0–1]	0.813
AAST grade of liver injury			0.146
III	12 (16%)	10 (31%)	
IV	44 (58%)	17 (53%)	
V	20 (26%)	5 (16%)	
First ED vital signs			
SBP <90	18 (24%)	10 (32%)	0.402
HR >120	20 (27%)	5 (16%)	0.219
GCS <9	5 (8%)	4 (13%)	0.461
Peak serum bilirubin, mg/dL	6.9 [1.7–25.0]	6.0 [2.4–35.5]	0.685
Daily drain output on day of diagnosis, mL	320 [180–720]	138 [85–330]	0.010
Hospital LOS	29 [16–46]	17 [12–28]	0.007
ICU LOS	7 [3–20]	5 [2–13]	0.331
Ventilator days	5 [1–15]	3 [0–7]	0.260

Continuous variables are presented as median [interquartile range]. Categorical variables are presented as number (percentage).

Patients with bile leak and intervention are defined as patients who underwent ERCP, operative intervention (exploratory laparotomy), or percutaneous transhepatic cholangiography.

Patients with bile leak and no intervention are defined as patients managed with drains alone (either percutaneous drains placed by radiology or surgical drains already in situ).

AIS, Abbreviated Injury Scale; ISS, Injury Severity Score.

TABLE 5. Multivariable Analysis of Independent Factors Associated With Bile Leak After Severe Liver Trauma

			95% CI	
	p	OR	Lower	Upper
Age	0.250	0.991	0.975	1.007
Male sex	0.014	2.107	1.161	3.824
Penetrating mechanism	<0.001	2.239	1.406	3.565
ISS	0.891	0.999	0.978	1.020
AAST grade of liver injury				
III	Ref			
IV	<0.001	4.463	2.571	7.747
V	<0.001	7.168	3.556	14.449
SBP <90 mm Hg	<0.001	3.301	1.927	5.657
HR >120 beats per minute	0.059	1.680	0.980	2.878
GCS <9	0.001	0.258	0.113	0.591

Multivariable analysis with logistic regression. Test for collinearity was performed before analysis. Area under the receiver operating characteristic curve, 0.794 (95% CI, 0.748–0.841).

CI, confidence interval; GCS, Glasgow Coma Scale; HR, heart rate; ISS, Injury Severity Score; Ref, reference; SBP, systolic blood pressure.

Bile leak was most commonly diagnosed on hospital day 6 [4–10] based on surgical drain output (n = 37 [39%]) or computed tomography scan (n = 34 [36%]) (Table 2). On the day of bile leak diagnosis, drain output among patients with a surgical drain in situ was 270 mL/24 hours [125–555 mL]. Other diagnostic investigations, such as hepatobiliary iminodiacetic acid scan, are summarized in Table 2 and were used less frequently. Bile was sent for culture in approximately half of patients with bile leak (n = 46 [43%]). Most of these biliary cultures yielded no growth (n = 21 [46%]). When organisms were isolated, the most common were *Candida* or other yeast (n = 6 [13%]), *Enterococcu*s (n = 6 [13%]), and *Pseudomonas* (n = 6 [13%]). Peak serum bilirubin among patients with bile leak was 6.7 [1.9–25.0] mg/dL or 115 [32–428] μmol/L in the International System of Units.

In terms of bile leak management, ERCP was the most frequent management strategy (n = 59 [55%]), followed by drain placement alone (n = 32 [30%]), operative intervention via exploratory laparotomy (n = 16 [15%]), and PTBD (n = 1 [<1%]) (Table 3). The ERCP was typically performed on hospital day 13 [8–18] and involved both stent placement and sphincterotomy (n = 33 [56%]). The ERCP failed to resolve the bile leak in 15 patients (25%), with at least 1 additional intervention pursued. One third of patients (n = 32) were managed with external drains alone (Table 3). Twenty-one (66%) of these patients were managed with surgical drains already

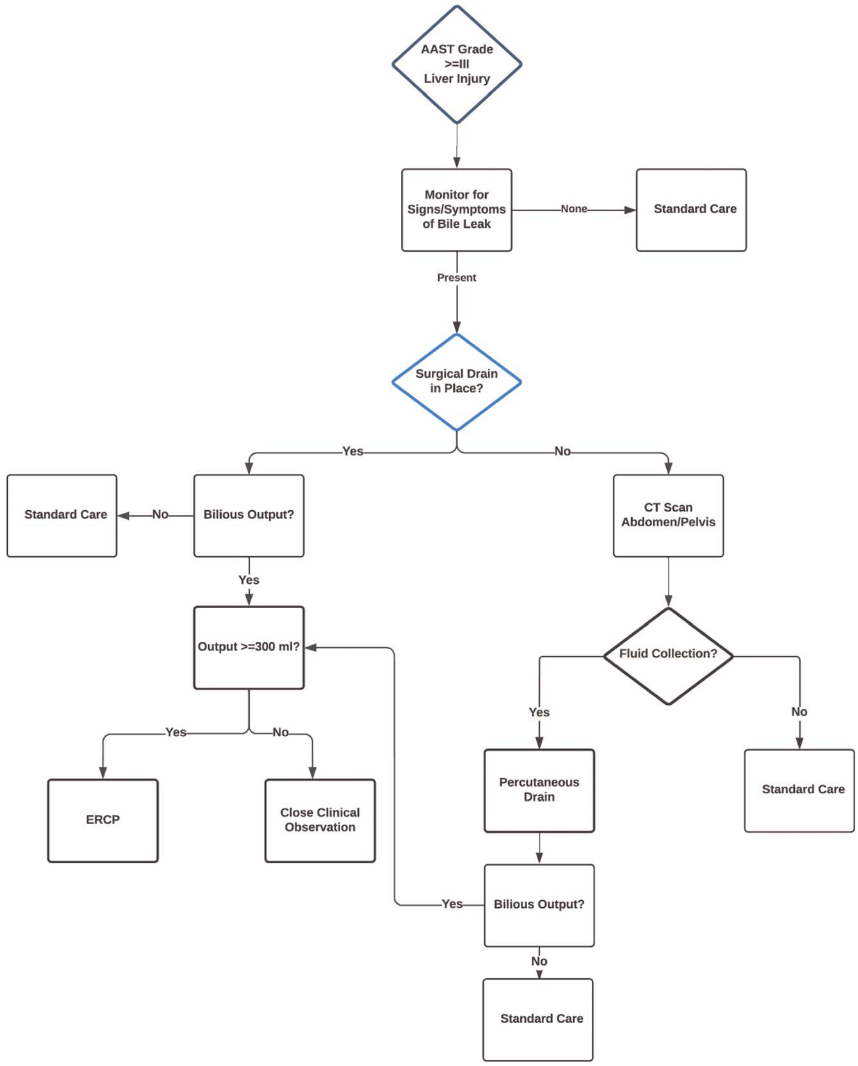

Figure 1. Proposed management algorithm for bile leaks after severe liver trauma. CT, computed tomography.

in place, and 11 patients (34%) underwent percutaneous drain placement.

Severe liver injury patients with bile leak were then compared based upon management strategy: patients who underwent intervention (ERCP, surgery, or PTBD) for their bile leak (n = 76 [70%]) versus those who did not (drainage alone) (n = 32 [30%]) (Table 4). These two groups were comparable in terms of demographics, injury mechanism, injury severity, AAST grade of liver injury, ED vitals, and peak serum bilirubin ($p > 0.05$). Patients undergoing intervention for bile leak had significantly higher drain output on the day of diagnosis than did patients who were managed with drainage alone (320 [180–720] vs. 138 [85–330] mL, $p = 0.010$). Patients who underwent intervention had longer hospital LOS (29 [16–46] vs. 17 [12–28] days, $p = 0.007$) but similar ICU LOS and ventilator days ($p > 0.05$).

Multivariable analysis with logistic regression of independent factors associated with bile leak after severe liver injury revealed that male sex (OR, 2.107; $p = 0.014$), penetrating mechanism of injury (OR, 2.239; $p < 0.001$), AAST grades IV (OR, 4.463; $p < 0.001$) and V (OR, 7.168; $p < 0.001$) liver injury, and initial ED systolic blood pressure <90 mm Hg (OR, 3.301; $p < 0.001$) were associated with increased odds of bile leak (Table 5). First ED Glasgow Coma Scale score of <9 was associated with reduced odds of bile leak (OR, 0.258; $p < 0.001$). No variables were independently associated with the use of ERCP after development of bile leak ($p > 0.05$) (Supplemental Digital Content, Supplementary Table 1, http://links.lww.com/TA/C654).

Receiver operating characteristic curve analyses of patients with bile leak who had a surgical drain in situ at the time of diagnosis were performed to identify the drain output cutoff points for bile leaks managed with ERCP. Drain output on the day of diagnosis and on post diagnosis day 3 had moderate diagnostic accuracies (area under the receiver operating characteristic curve of 0.636 and 0.623, respectively) in the prediction of the use of ERCP. Using cutoff points optimized for sensitivity and specificity, the day of diagnosis cutoff point was a drain output of 390 mL (Supplemental Digital Content, Supplementary Fig. 1, http://links.lww.com/TA/C655), and the postdiagnosis day 3 cutoff point was a drain output of 213 mL (Supplemental Digital Content, Supplementary Fig. 2, http://links.lww.com/TA/C655). On the basis of these study findings, a potential management algorithm is proposed (Fig. 1).

DISCUSSION

In this study, patients with high-grade liver injuries developed bile leaks in approximately 5% of cases, which is consistent with existing literature.[1,3,13,14] Independent factors associated with bile leak development after severe liver trauma in this study were intuitive and reflective of existing single-center studies, including penetrating injury mechanism, AAST grades IV and V injury[1,13,15,16] and ED hypotension. These are clinically useful findings for trauma surgeons because they allow for a heightened index of suspicion for bile leak development in such patients, which in turn may facilitate prompt diagnosis and timely management.

Our multicenter study found that bile leaks after severe liver trauma were typically diagnosed on hospital day 6. Diagnosis was often predicated on computed tomography scan and/or the surgical drain output, at a median of 270 mL on the day of diagnosis. Despite similar patient demographics and injury severity, only drain output volume differed between patients who underwent ERCP, PTBD, or surgery for bile leak management as compared with patients who were managed with drains alone. Patients who underwent intervention to manage their bile leak displayed a median of 320 mL of bilious output on the day of diagnosis, whereas patients managed with drainage alone had a median output of 138 mL. Although the receiver operating characteristic curve analyses in our study had only moderate diagnostic accuracies, the day of diagnosis drain output cutoff point for use of ERCP was an output of 390 mL.

Drain volume is of particular interest since current literature suggests that drain output may predict need for intervention, specifically internal biliary drainage (i.e., typically ERCP guided biliary stent and occasionally PTBD), after bile leak in severe liver injury. One small study advocated for percutaneous drainage alone for bile leaks with an output of <400 mL/d.[11] These findings were supported by a larger single-center study in South Africa of 51 patients with bile leaks following liver trauma, in which leaks with output of <400 mL/d and those without continued drainage beyond 14 days were managed with observation or percutaneous drainage.[10] With this approach, 65% of bile leaks in that series were managed nonoperatively and without internal biliary drainage, all cases of which were successful. This concept is reinforced in a recent review article on hepatobiliary trauma, which encourages surgeons to wait to pursue ERCP and biliary stenting for >1 to 2 weeks after bile leak diagnosis.[9]

Overall, our multicenter study data validate several smaller, single-center studies[10,11] that encourage the pursuit of ERCP for bile leaks that exceed 300 to 400 mL/24 hours of bilious drain output at the time of diagnosis, with lower volume leaks managed with percutaneous drainage alone. One third of our bile leaks were managed with external drainage alone, a rate that is comparable with existing single-center studies.[15,17] Therefore, we propose that bile leaks with an initial output of <300 mL/24 hours be managed with close clinical observation, with reservation of ERCP for higher volume leaks. Because our data are retrospective in nature, this suggestion will need to be validated by prospective examination in the future.

In the current study, approximately half of the bile leaks were managed with ERCP with an appropriately low rate of post-ERCP pancreatitis (2%) and an acceptable rate of failure (25%), defined as the performance of additional intervention for bile leak management following ERCP. Unfortunately, we were unable to identify factors independently associated with use of ERCP after bile leak. This information would be useful to clinicians in the decision making surrounding the need for and optimal timing of internal biliary drainage after bile leaks. This indicates a further need for examination of bile leaks after severe liver trauma to more precisely define the optimal management strategy. One also wonders if variability in access to ERCP, percutaneous drainage, and/or hepatobiliary subspecialty back-up across individual centers also impacts the timing and specific selection of interventions for ongoing bile leaks following severe liver injuries.

The study limitations must be considered in the interpretation of these findings. First, this was a retrospective observational study and carries the inherent limitations of this type of study design. Specifically, this is a description of how bile leaks are currently managed at 10 participating North American trauma centers and not necessarily how they ought to be managed. For example, it is possible that all bile leaks, regardless of initial output, may be self-limited with percutaneous drainage alone. This possibility cannot be ascertained with retrospective observational examination and will require further study. However, we think that these data still represent an important first step toward the delineation of the optimal management of bile leaks. In addition, the management of bile leaks after severe liver injury in this series was not protocolized, either within individual centers or across participating centers, and may also have varied by study year. Therefore, there is likely to be heterogeneity in the study data on diagnosis and management strategies, which may impact study generalizability. Lastly, this study included both blunt and penetrating bile leaks. It is possible that the optimal diagnosis and management of bile leaks may be predicated upon injury mechanism, and therefore, this is a further source of potential heterogeneity in the dataset. In the future, these limitations could be addressed with a larger multicenter study performed with a prospective and protocolized design to further refine the ideal management of bile leak following severe liver injury.

To conclude, bile leaks in this North American multicenter study of patients with severe liver trauma were most likely to be self-limited and amenable to percutaneous drainage alone when they were smaller volume. Leaks in excess of 300 to 400 mL on the day of diagnosis were more likely to undergo ERCP, PTBD, or surgical intervention. On balance, this multicenter study serves to confirm several smaller single-center studies on the management of bile leaks following severe liver injury. Endoscopic retrograde cholangiopancreatography remains the mainstay of therapy for bile leaks undergoing intervention and fortunately carries a relatively high rate of success with a low associated rate of complications. We propose that, once external drainage of a bile leak has been established (via percutaneous drain insertion or via an existing surgical drain), ERCP should be reserved for bile leaks that exceed a daily output of 300 mL, with close clinical observation of smaller-volume leaks. Because these recommendations are based on retrospective observational examination, the data from this multicenter study must be validated in the future with prospective study.

AUTHORSHIP

M.S. and C.G.B. provided the study concept. All authors contributed to the data collection. M.S. and N.O. performed the data analysis. M.S., C.G.B., and K.I. performed the data interpretation. All authors participated in writing and critically reviewing the final manuscript.

DISCLOSURE

The authors declare no conflicts of interest.

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