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Bile Leak Following Liver Trauma: Diagnosis and Management from a Trauma Centre with Matched Controls

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Abstract

Background: Bile leaks are a well recognised complication following liver trauma, however the incidence is rare, and literature is limited. The aims of this study were to identify incidence, risk factors, diagnosis, and management of bile leaks from a large cohort of liver trauma patients.

Methods: All patients with liver trauma over a 15-year period at a trauma centre were retrospectively reviewed using data from a prospective trauma registry. Clinical records, radiology, and laboratory data were reviewed. A comparative analysis compared patients with bile leaks to liver injury grade matched controls.

Results: From this cohort of 473 patients with liver trauma, 31 (6.6%) had a bile leak. High grade injury was a risk factor, occurring in 30% of these patients, as well as parenchymal damage extending into the porta-hepatis. Serum bilirubin levels over 40 µmol/L were predictive of a bile leak. Endoscopic biliary decompression with a transampullary stent was the most common management technique. Surgical management associated with high bile drainage volumes.

Conclusion: Bile leak as sequelae of liver trauma occurs in high grade injuries. Serum bilirubin levels over 40 µmol/L are predictive of bile leak. Most cases are managed with endoscopic decompression; however, high volume drainage is associated with definitive surgical management.

Keywords: Bile leak • Liver trauma • Liver injury • Serum bilirubin

Introduction

Bile leaks are a well-recognized complication following blunt and penetrating liver trauma with a reported incidence ranging from 0.5% to 20% [1,2]. Previous studies have identified risk factors for the development of traumatic bile leak including high grade and central Couinaud segment parenchymal injuries, non-selective trans-arterial embolization for bleeding and operative management [2-4]. Identification of bile leak requires a high index of suspicion due to non-specific symptoms and signs which may result in difficulty and delayed diagnosis. Previous studies have reported that endoscopic retrograde cholangiopancreatography (ERCP) with trans-ampullary stenting and percutaneous abdominal drainage procedures form the basis of treatment for the majority of post-traumatic bile leaks [5], with success rates ranging from 90% to 100% [6,7]. Some studies advocate for early ERCP within 24 hours of diagnosis [8], however some data has demonstrated minor leaks (<400ml/24h) may be managed conservatively without the need for ERCP [2,4].

Evidence for serum bilirubin monitoring in bile leak detection following liver trauma is limited. Biochemical jaundice in multi-trauma patients may be multifactorial and include haemolysis of extravasated or transfused blood, hepatic dysfunction from systemic hypotension, haemodynamic shock, and sepsis [9]. Yuan KC, et al. [10] determined that a serum bilirubin of 43 µmol/L could provide a sensitivity of 100% and specificity of 85.1% for predicting bile leak, using retrospective data from their small series of 14 patients with bile leaks from a cohort of 288 patients with blunt liver trauma. The aim of this study was to identify the incidence and risk factors for bile leakage as sequelae of liver trauma, and evaluate the diagnosis and management of bile leaks, including a comparison with liver injury grade matched controls.

Methods

We conducted a retrospective cohort study including all liver trauma patients over age 15 admitted to Auckland City Hospital, which provides tertiary level trauma and hepatobiliary units, from January 2006 to January 2021. Some patients were initially treated in other hospitals in New Zealand and were transferred to Auckland City Hospital for tertiary management. Clinical data was retrieved retrospectively from a prospective trauma registry in accordance with local ethical protocols and approval. Electronic medical records, clinical notes, radiology, and laboratory data were reviewed. Liver trauma was graded using the American Association for the Surgery of Trauma (AAST) organ injury scale (OIS) 2018 revision for liver trauma [11].

We defined a bile leak as follows: (1) Clinically by the unequivocal presence of frank bile intra-operatively or through a surgically or percutaneously placed drain, (2) Biochemically if aspirated or drain fluid bilirubin was greater than 3 times the serum bilirubin level or (3) Radiologically with a cholangiogram demonstrating contrast leakage. We deemed Computed Tomography (CT) scans demonstrating ascitic fluid and/or elevation of serum bilirubin in isolation insufficient for confirmation of diagnosis.

Comparative Analysis

Thirty matched control patients (without bile leak) were selected for the comparative analysis. AAST liver injury grade and patient injury severity scores (ISS) were compared between the two groups to assess for confounding by selection bias [12]. Laboratory data for patients in the bile leak group was compared to patients in the control group. This included admission serum bilirubin level and serum bilirubin level at the time of diagnosis, and the peak level for patients in the control group. Patients' CT imaging was reviewed

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for identification of parenchymal damage extending into the porta-hepatis. Clinical details on bile leak diagnosis and intervention were reviewed as well as radiological imaging. Definitive management of a bile leak was defined as a procedure (surgical or endoscopic) which aimed to prevent the leakage of bile. Abdominal drainage procedures (surgical or percutaneous) were recorded separately. The drainage of bile volume per 24 hours prior to the definitive procedure when applicable or the peak output for those managed conservatively was documented.

Statistics

The statistical analysis was performed using SPSS version 27.0 (IBM, Armonk, NY, USA). Categorical data is expressed as percentage or frequency and analysed using Fisher exact and Chi Square tests with an alpha significance level of p=0.05. Numerical data are presented as mean and standard deviation and analysed with two-tailed T-tests. For the assessment of the serum bilirubin level, a one-tailed T-test was used due to the clear elevation in serum bilirubin levels in bile leak patients. One-way ANOVA was used for the comparison of mean drain volumes by definitive management technique.

Results

From January 2006 to January 2021, 473 patients were hospitalised with liver trauma. Of these patients, 31 were diagnosed with a bile leak (6.6%). All bile leaks occurred in patients with grade III to V injuries. 30% of patients with high grade injuries (IV and V) developed a bile leak, (odds ratio (*OR*)=40.0, 95% CI (13.5, 118.1) (Table 1).

There was no significant difference in AAST injury grade between the control group and the bile leak group, confirming the achievement of adequate grade-matching (Table 2). These groups were also well matched for injury severity scores (ISS). Parenchymal damage extending into the porta-hepatis was more common in bile leak patients (p=.005). There was a significant difference in the mean admission serum bilirubin level (p=.013), however both groups were still within the normal range except for a single recording in the bile leak group of 31 µmol/L. Bile leak patients had significantly higher mean serum bilirubin level (mean (M)=58.3 µmol/L, standard deviation (SD)=28.5) compared to control group patients (M=18.5 µmol/L, SD=9.1) measured at the time of bile leak diagnosis and peak levels respectively (p=< .001) (Table 2 and Figure 1).

Bile leak was most frequently diagnosed by percutaneous aspiration or operative findings of intra-abdominal bile (Figure 2). The median time of diagnosis was 4 days after injury (range 1 to 12 days). ERCP was the most common definitive management technique for bile leak, followed by liver resection. Hepaticojejunostomy was performed in two patients (Figure 3). One patient had an ERCP on day 4, followed by a right hemi-hepatectomy on day 13 after delayed haemorrhage. Of the 10 patients who had definitive operative management for bile leak, 4 had a complete lack of intrahepatic duct filling on cholangiogram compared to none of the 19 patients who had ERCP only (Table 3). Abdominal drainage of bile was achieved using a variety of different methods (Figure 4). Patients who were managed conservatively had lower drain volumes/24h (M=383 ml/24 h, SD=304) compared to patients who were managed with ERCP (M=807 ml/24 h, SD=944) or with surgery (M=2136 ml/24 h, SD=1383) (Figure 5), however this difference was not statistically significant (f=4.04, p=0.033).

Discussion

In this study, the overall incidence of bile leak following liver trauma was 6.6%. High grade injuries were found to be a significant risk factor, consistent with previous studies in the literature [2-4,10]. In fact, 30% of patients with high grade liver injuries from our cohort developed a bile leak. There was also an association between bile leak and injury extending into the porta-hepatis (OR 5.75). Our data also shows higher serum bilirubin levels in patients with bile leaks compared to grade matched controls. Of note, no patient in the control group had a peak serum bilirubin level exceeding 40 µmol/L. Therefore, serum bilirubin should be considered a useful tool in the clinical setting, where levels greater than 40 µmol/L are strongly predictive of bile leak. Our analysis of means also showed a significant difference in the admission serum bilirubin levels between groups, however when a normal cut-off value of 25 µmol/L was used this difference was no longer significant suggesting a mildly elevated serum bilirubin level, yet still within the normal range, may warrant extra vigilance for bile leak.

Intra-operative and percutaneous diagnosis occurred equally in this cohort, with bile in previously placed surgical drains and ERCP less common. Drainage of intraperitoneal bile was often (35%) achieved through drains already in place prior to the development of bile leakage. However, 45% of patients had bile drained at either laparotomy, laparoscopy, or by laparotomy or laparoscopy after initial percutaneous drainage (Figure 4). Most of the patients who underwent drainage surgically required liver resection or hepaticojejunostomy, and the indication for operation was therefore the

Table 1. Liver injury AAST grade for bile leak patients compared to all liver trauma.

AAST Grade	Bile Leak	Liver Trauma without Bile Leak	p-value
Grade I & II	0	260	-
Grade III	4	113	< .001
Grade IV & V	27	63	

n.b. 6 patients that died within 24 hours of injury were excluded (4 grade V, 1 grade IV, 1 grade III).

Table 2. Comparison of bile leak and AAST grade matched patient controls.

AAST Grade	Bile Leak (n=31)	Control (n=30)	p-value
Liver injury AAST grade			0.508
III	4	6	
IV & V	27	24	
Injury severity score (ISS) M (SD)	28.6 (9.3)	25.3 (12.3)	0.248
Admission serum bilirubin µmol/L M (SD)	11.0 (6.7)	7.4 (3.5)	0.013
Admission serum bilirubin			0.492
Normal range (1-25 µmol/L)	28	30	
Elevated (>25 µmol/L)	1	0	
Not recorded	2	0	
Porta-hepatis involvement			0.005
Yes	22	10	
No	9	20	
Serum bilirubin at time of bile leak diagnosis (peak for control group) µmol/L M (SD)	58.3 (28.5)	18.5 (9.1)	<.001

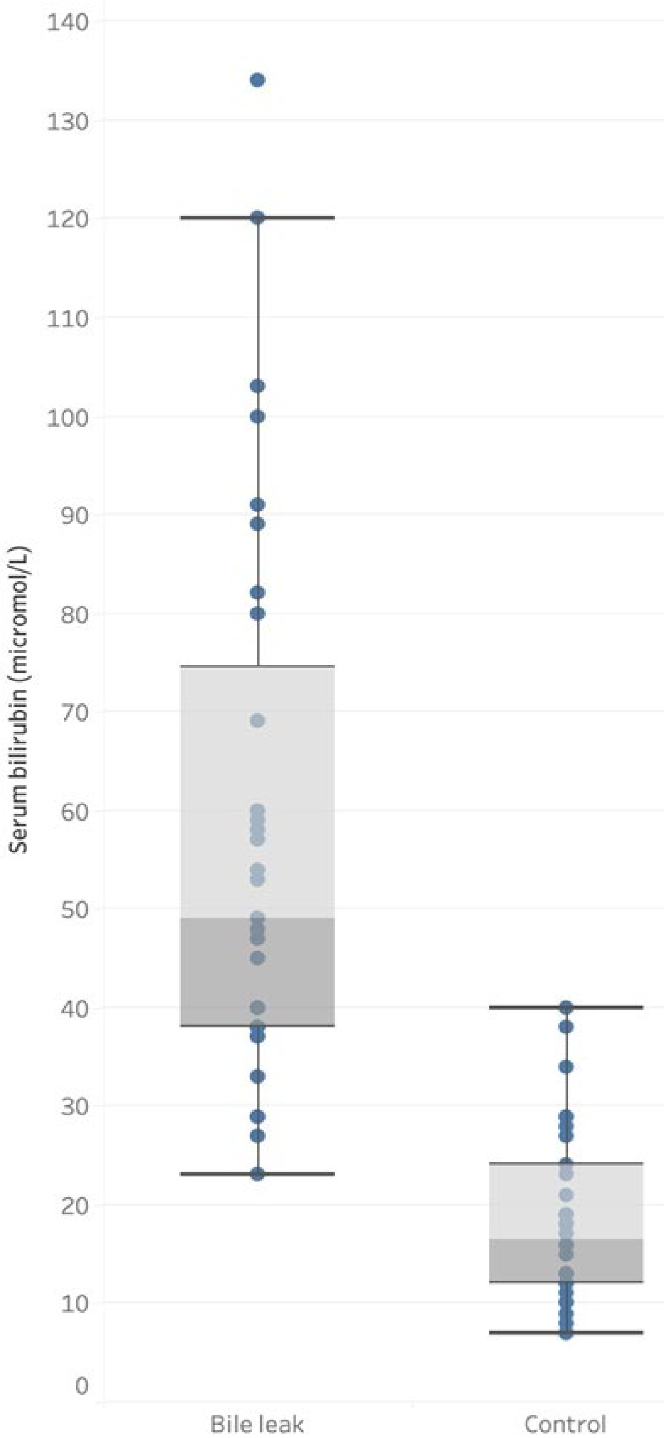

Figure 1. Serum bilirubin levels at time of diagnosis in bile leak patients compared to peak levels in grade matched controls.

definitive surgical procedure, rather than drainage per se. Only one laparotomy was performed purely for peritoneal lavage. Percutaneous drainage was performed in 29% of patients, with nearly half of these patients subsequently undergoing surgical drainage (Figure 4). One such patient had 3000 ml of bile drained after percutaneous drain insertion, and had an ERCP demonstrating central duct contrast extravasation and a complete lack of intrahepatic duct filling. This patient went on to undergo laparotomy and hepaticojejunostomy for an avulsed left hepatic duct, thus not surprising that percutaneous and endoscopic management did not suffice.

We found a comparatively low number of conservatively managed patients (9.7%) with a clear predominance for ERCP (61.3%), followed by surgery (32.3%). In addition, all patients with complete lack of intrahepatic duct filling on cholangiogram underwent definitive surgical management. Our data regarding

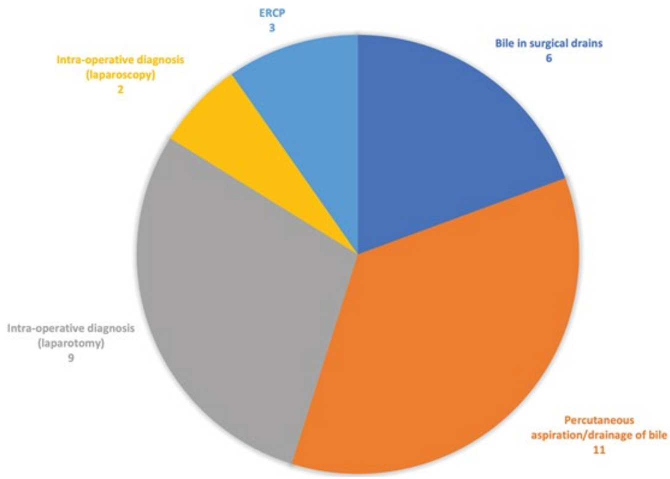

Figure 2. Bile leak diagnostic method.

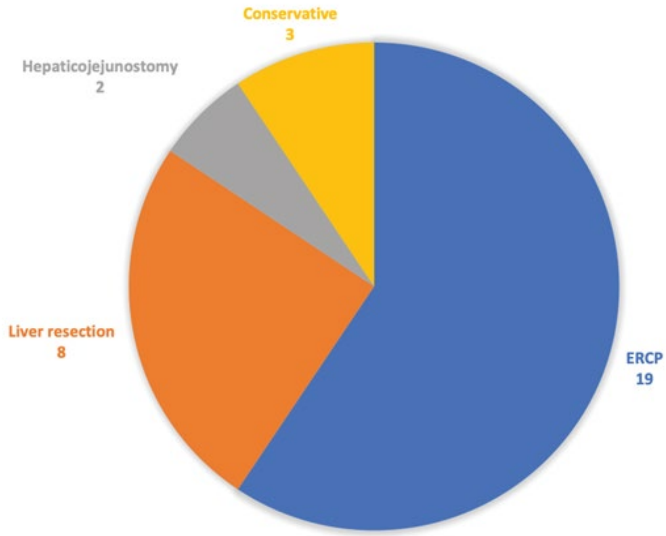

Figure 3. Bile leak definitive management technique.

Table 3. Cholangiogram findings for patients managed with ERCP compared to surgery.

Cholangiogram Findings	ERCP	Definitive Surgical Management*	p-value
Absence of intrahepatic duct filling	0	4	0.009
Intrahepatic duct filling	19	6	
*Hepatic resection or hepaticojejunostomy			

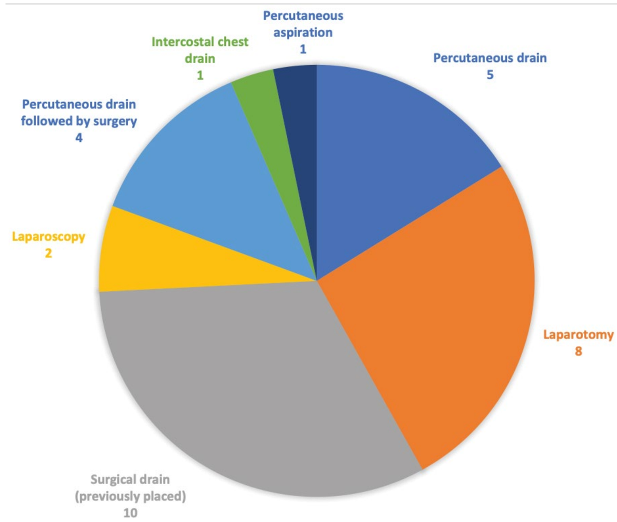

Figure 4. Abdominal drainage method.

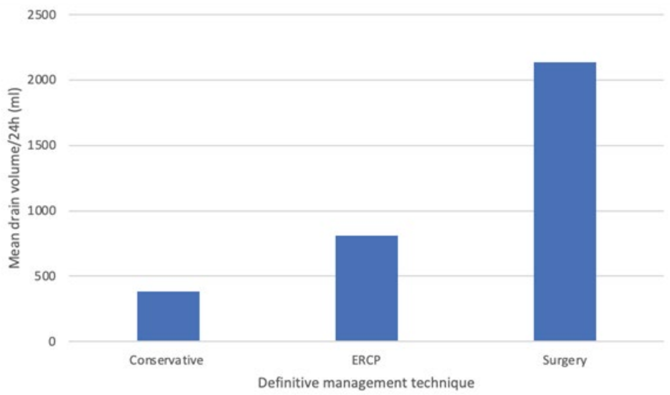

Figure 5. Mean drain volume/24 h (ml) associated with definitive management technique.

surgical repair rate is similar to that reported by Zakaria HM, et al. (29.1%) [4], and is most often reserved for complex patients who had failure of other management techniques. This differs from the findings of Oo J, et al. [3] of successful conservative management in 41.9% of patients; however a similar proportion (67.7%) underwent ERCP. Complications of ERCP in this setting have previously been described leading to a recommendation that it should be reserved for major leaks [2]. On the contrary, some authors have supported early utilisation as soon as the bile leak becomes apparent to minimize the development of associated complications [8,10]. This approach, however, may not take into consideration the possibility of spontaneous resolution of a bile leak provided there is adequate drainage [2]. Our data has also shown that higher bile drainage/24 h is associated with surgical management to address the underlying biliary injury. Moderate drainage volumes were associated with ERCP as the definitive management technique, and patients successfully managed conservatively had lower volumes. Although this association was not statistically significant, this is likely to be a type II statistical error due to the low number of events. Hommes M, et al. defined major bile leak as drainage of greater than 400 ml/day or persistent drainage of greater than 50 ml/day for longer than 14 days. Minor leaks (<400 ml/24 h) were managed conservatively and major leaks underwent ERCP within 24 hours [2]. Cogbill T, et al. [13] suggested that further evaluation of a biliary fistula was indicated when drainage of bile was greater than 300 – 400 ml/24h. Our data supports existing evidence that managing bile leaks <400ml/24h conservatively may represent a valid option.

As with much of the literature on traumatic bile leak, this study is limited by the retrospective nature and small study population which renders it susceptible to statistical error. Nevertheless, our series includes 31 patients with bile leak which is one of the largest reported in modern trauma literatures. Further research with a multicentre design could address these specific limitations to further ascertain best clinical management.

Conclusion

Bile leak is the most common complication following liver trauma, and high grade injuries with extension into the porta-hepatis are significant risk factors. Our data suggests that a serum bilirubin level over 40 μmol/L is strongly predictive of a bile leak following liver trauma. Most leaks can be successfully managed with abdominal drainage and ERCP, however high drain volumes and lack of intrahepatic duct filling on cholangiogram are associated with a need for definitive surgical management. A small proportion of patients with low drain volumes can be successfully managed conservatively

Declarations

Ethics approval

Clinical data was retrieved retrospectively from a prospective trauma registry in accordance with local ethical protocols and approval at Auckland City Hospital. Consent to participate was not required.

Availability of data

All data analyzed during this study are included in the final article. Raw datasets are available from the corresponding author on reasonable request.

Conflicts of interest

The authors declare that they have no competing interests.

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Author contributions

NJF undertook the study conception, design and data collection. Formal data analysis and interpretation, and first draft of the manuscript were written by TL and both authors reviewed and edited further versions of the manuscript. Both authors read and approved the final manuscript.

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