RESEARCH ARTICLE

Early postoperative outcomes in patients with resectable extrahepatic biliary tumours: A single center retrospective cross sectional study

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Abstract

Objective: To evaluate early postoperative outcomes in patients having undergone surgery for extrahepatic biliary tumours.

Method: The retrospective chart review was conducted in January 2023 at the Aga Khan University Hospital, Karachi, and comprised data of patients who underwent surgical resection of extrahepatic biliary tumours, including hilar cholangiocarcinoma, gallbladder cancer, distal common bile duct tumours and undifferentiated ampullary tumours, between January 2011 and June 2022. Outcomes were assessed in terms of morbidity and 90-day mortality, and the risk factors were determined. Data was analysed using SPSS 25.

Results: Of the 81 patients, 47(58%) were males and 34(42%) were females. The overall mean age of the sample was 57.8+-11.4 years. The most common clinical presentation was jaundice 47(58%), while the most frequent site of lesion was ampullary region 50(62%), followed by the gallbladder 22(27%), and the hilar region 9(11%). Postoperative complications were observed in 42(52%) patients, including surgical complications in 28(34.5%). Anastomosis leak was observed in 3(3.7%) patients, and 1(1.23%) required re-exploration. Mortality rate at 90-days was 5(6.2%). The presence of more than two co-morbids and blood loss >500ml were significantly associated with adverse postoperative outcomes (p=0.002). Blood loss >500ml was also associated with 30-day mortality (p=0.003).

Conclusion: The overall postoperative outcomes of surgically resected extrahepatic biliary tumours were satisfactory.

Key Words: Hepatobiliary, Cholangiocarcinoma, Extra-hepatic biliary tumours, Undifferentiated ampullary tumours, Gallbladder carcinoma.

(JPMA 75: 1569; 2025) **DOI: https://doi.org/10.47391/JPMA.21670**

Introduction

Extra-hepatic biliary tumours (EBT) comprise hilar cholangiocarcinoma (CC), gallbladder cancer (GBC), distal common bile duct (CBD), or distal cholangiocarcinoma (DCC), and undifferentiated ampullary tumours. Despite significant advances in techniques and technology, management of these tumours poses a challenge to the surgeons due to their aggressive nature and high postoperative complications. Approximately 10-40% of these tumours are amenable to resection at the time of diagnosis and even those that are surgically resected have an estimated 5-year survival rate <20%.[1-2] In 2017, there were 210,878 new EBT cases and intrahepatic cholangiocarcinoma reported globally, with the highest incidence and mortality rates being in the Asia-Pacific region.[3]

Although grouped together as biliary tumours, EBT is a diverse group of cancers with management based on the organ involved and stage of the disease. GBC is relatively rare and constitutes about 1.3% of the global cancer burden.[4] Surgical resection remains the only potential cure and is dependent on tumour (T) staging.[5] Laparoscopic cholecystectomy alone is sufficient for T1a tumours. However, higher-stage tumours require a radical cholecystectomy with hepatic segment resection (minimum) and lymph node (LN) dissection. More advanced tumours, including T3, T4 stages, may require major hepatectomy or en-bloc resection of adjacent organs to achieve a negative resection margin. Such advanced procedures carry approximately 1-5% risk of mortality.[5-6]

Hilar CC, or Klatskin tumours, are the most common type of bile duct cancer and constitute around two-thirds of all bile duct tumours. Of these, approximately 70% are deemed potentially resectable tumours.[7] In order to achieve oncological margins, resection for Klatskin tumours has evolved over time from resection of biliary tree only to major hepatic resection with biliary resection, lymphadenectomy and reconstruction. DCBD tumours constitute approximately 20-30% of all bile duct tumors,8 including undifferentiated ampullary tumours. The primary surgical procedure for these tumours is Whipple's

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Submission complete: 24-08-2024 **First Revision received:** 22-11-2024
Acceptance: 19-07-2025 **Last Revision received:** 18-07-2025

procedure that has been shown to improve the long-term survival rate.[8]

With the recent advances in radiology and endoscopic evaluation of biliary tumours, early detection has improved considerably, but surgical resection is still very demanding and is carried out only in specialised centres with high morbidity and mortality rates. The current study was planned to evaluate early postoperative outcomes in patients having undergone EBT surgery.

Materials and Methods

The retrospective chart review was conducted in January 2023 at the Aga Khan University Hospital (AKUH), Karachi, and comprised data of patients who underwent surgical EBT resection, including hilar CC, GBC, DCC and undifferentiated ampullary tumours, between January 2011 and June 2022.

Data of all patients aged at least 18 years who underwent surgical resection for histologically confirmed EBT was included, provided a follow-up data of at least 90 days was available. The rest of the cases were excluded.

All the patients had undergone oncological resection depending on the location and extent of the tumour. Lymphadenectomy and organ resection were done where appropriate. All the surgical specimens had been sent for histopathological grading and staging of the disease.

The primary endpoints of the study were 90-day mortality and postoperative complications graded according to the Clavien Dindo Classification of Surgical Complications.[9] The secondary outcomes were intensive care unit (ICU) stay and the length of hospital stay (LOS).

Data was analysed using SPSS 25. Quantitative variables, like age, body mass index (BMI), blood loss, length of hospital stay (LOS) and duration of intensive care unit (ICU) stay, were reported as mean +/- standard deviation, whereas qualitative variables, like gender, histopathology and tumour location, were reported as frequencies and percentages. The association of quantitative variables with the outcomes (morbidity and mortality) was assessed using independent t test. Prior to conducting the analysis of variance (ANOVA) test, data normality was checked to ensure that the assumptions of normality and homogeneity of variance were met. The association of qualitative variables with the outcome was assessed using chi-square and one-way ANOVA tests. $P<0.05$ was considered significant.

Results

Of the 81 patients, 47(58%) were males and 34(42%) were females. The overall mean age of the sample was 57.8+-11.4 years. The most common clinical presentation was jaundice 47(58%), while the most frequent site of lesion was the ampullary region 50(62%), followed by the gallbladder 22(27%), and the hilar region 9(11%). All the 81(100%) patients underwent standard preoperative assessment, including computed tomography (CT) scan and endoscopic retrograde cholangiopancreatography (ERCP), as indicated. 36 (44.4%) patients required preoperative biliary drainage for optimisation of bilirubin levels prior to the surgery which included drainage by ERCP or percutaneous transhepatic biliary drainage (PTBD). In 20(22.7%) patients, CT scan could not detect a primary lesion due to sub-centimeter size. These tumours were located in the periampullary region. and other CT findings, such as biliary dilatation, were suggestive of an obstructing lesion at that site. Demographic and clinical data was noted in detail (Table 1).

Table-1: Descriptive characteristics.

Variables	n (%)	Mean (SD)
Age (years)		57.8(+-13)
Body Mass Index		25.2(+-5.7)
Preoperative biliary stent		
External	6 (7.4)	
Internal	28 (34.6)	
Combined internal-external	2 (2.5)	
Preoperative biopsy	35 (43.2)	
Duration of operation (minutes, mean, range)		337.3 (+-137.3)
Blood loss (ml, mean, range)		660.8 (+-725.0)
pT stage		
T1	13(16)	
T2	41(50.6)	
T3	23(28.4)	
T4	2(2.5)	
pN stage		
N0	45(55.6)	
N1	32(39.5)	
N2	3(3.7)	
Final stage		
Stage I	21(25.9)	
Stage II	20(24.7)	
Stage III	35(43.2)	
Stage IV	4(4.9)	
Total length of stay (days, mean, range)		11.7 (+-8)
ICU stay (days, mean, range)		0.6 (+-5.8)
Adjuvant therapy	41(50.6)	

ICU: Intensive care unit, pN: Pathological regional lymph node, pT: Pathological tumour.

Of the patients who underwent surgery for GBC, 2(9%) had laparoscopic cholecystectomy alone, while 20(91%) underwent radical cholecystectomy with Couinaud segment IVB and V resection of liver and portal lymphadenectomy. Of these patients, 4(20%) underwent

an additional port site excision as the tumour was histopathologically identified in laparoscopic cholecystectomy specimen.

There were 8(9.8%) patients who underwent radical excision of CBD, and 3(36.4%) of them required a major hepatic resection. One (33.3%) of these patients had a CC that was encasing the right hepatic artery and the right portal vein. An anatomical right hepatectomy was performed. During the procedure, the lateral wall of inferior vena cava had an iatrogenic rent that was repaired. There was 1(33.3%) patient with a CC involving the left hepatic duct. A formal left hepatectomy was done in this patient. There was 1(33.3%) patient having a CC with the involvement of gallbladder. An extended right hepatectomy was performed. The remaining 5(62.5%) patients had tumour in the mid to distal CBD without the involvement of right or left bile duct or confluence. In these patients, frozen section was sent to determine negative bile duct resection margins, and hepaticojejunostomy was done.

The most frequently performed procedure was pancreaticoduodenectomy 53(65.4%) for distal CBD and undifferentiated ampullary lesions. A classic Whipple procedure was performed, and the type of pancreatic anastomosis (pancreatojejunostomy vs gastrojejunostomy) was based on the surgeon's preference. The patients underwent a Witzel feeding jejunostomy.

Mean duration of surgery was 337.3±137.3 minutes and the mean estimated intraoperative blood loss (EBL) was 660.8±725 ml. A total of 41 (50.6%) patients required intraoperative transfusion of blood-related products.

Histopathology of the final specimen suggested 72(88.9%) patients had adenocarcinoma. Other histological types included papillary carcinoma 2(2.5%), squamous cell carcinoma 1(1.2%) and other pathologies 6(7.4%). According to grading, 59(72.8%) tumours were moderately differentiated, 15(18.5%) were well-differentiated and 5(6.2%) (n=5) were poorly differentiated. Complete macroscropic and microscopic (R0) resection was achieved in 95% patients. Perineural invasion was seen in 23(28.4%) patients, and 11(13.6%) patients had >2 LNs involved.

There were 4 (4.9%) patients who were eventually found to have metastatic disease after surgery. Among them, 2(50%) patients underwent radical cholecystectomy and had separate lesions away from the infiltrating gallbladder lesion in the resected liver. The other 2(50%) patients underwent Whipple procedure and had additional resection of liver nodule which was initially negative on frozen section, but final histopathology showed metastasis.

Table-2: Postoperative complications.

Complications	n (%)
Systemic	
Cardiac	4 (4.9)
Pulmonary	10 (12.3)
Others	3 (3.7)
Surgical	
Wound infection	9 (11.1)
Intra-abdominal abscess	10 (12.3)
Bleeding	3 (3.7)
Anastomosis leak	3 (3.7)
Bile leak	1 (1.2)
Paralytic ileus	1 (1.2)
Biliary sepsis	1 (1.2)
Liver failure	1 (1.2)

Mean LOS was 11.7±8 days and mean ICU stay was 0.6±5.8 days. Postoperative complications were observed

Table-3: Univariate analysis identifying the risk factors for surgical complications after extrahepatic biliary tumour (EBT) surgery.

Variables		Morbidity n(%)	p-value
Age	<60	25 (30.8)	0.777
	>60	17 (20.9)	
Gender	Male	25 (30.8)	0.777
	Female	17 (20.9)	
BMI	<19	1 (1.2)	0.122
	19-25	19 (23.4)	
	>25	21 (25.9)	
Two co-morbids		16 (19.7)	0.001
More than two co-morbids		26 (32.09)	
Biliary drainage		21 (25.9)	
No biliary drainage		21 (25.9)	
Albumin	<3.5	9 (11.1)	0.802
	>3.5	24 (29.6)	
ASA	I-II	22 (27.1)	0.551
	>II	20 (24.6)	
Type of procedure	Hilar	12 (14.8)	0.239
	Whipple	30 (37.03)	
Duration of procedure	>300min	10 (12.3)	0.097
	300min	32 (39.5)	
Blood Loss	<500 ml	19 (23.4)	0.002
	>500 ml	23 (28.39)	
Intra-operative transfusion		17 (20.9)	0.223
No intra-operative transfusion		22 (27.1)	
Perineural invasion		13 (16.0)	0.596
No perineural invasion		29 (35.8)	
Perivascular invasion		10 (12.3)	0.849
No perivascular invasion		32 (39.5)	

BMI: Body mass index, ASA: American Society of Anaesthesiologists.

Table-4: Univariate analysis identifying the risk factors for 90-day mortality after extrahepatic biliary tumour (EBT) surgery.

Variables		n(%)	p-value
BMI	<19	0 (0)	0.069
	19-25	4 (4.9)	
	>25	1 (1.2)	
Two co-morbids		5 (6.1)	0.233
More than two co-morbids		0 (0)	
Biliary drainage		2 (2.4)	0.836
No biliary drainage		3 (3.7)	
Albumin	<3.5	2 (2.4)	0.699
	>3.5	3 (3.7)	
ASA	I-II	3 (3.7)	0.836
	>II	2 (2.4)	
Duration of procedure	<300	0 (0)	0.112
(minutes)	>300	5 (6.1)	
Blood Loss	<500ml	0 (0)	0.003
	>500ml	5 (6.1)	

BMI: Body mass index, ASA: American Society of Anaesthesiologists

in 42(52%) patients (Table 2). As per Clavien-Dindo classification[9], the frequency of level III and above complications in the patients was 7(21%). There were 28(34.5%) patients who developed surgical complications and were managed accordingly. Anastomosis leak was observed in 3(3.7%) patients, out of whom 1(33.3%) required re-exploration and revision of pancreatico-jejunostomy. The other 2(66.6%) patients developed leaks at hepatico-jejunostomy site which were managed with stenting in 1(50%) and drain placement in 1(50%). There was 1(1.2%) patient who developed bile leak that was managed with endoscopic stenting. There were 10(12.3%) patients with intra-abdominal collection, and 4(40%) of them were conservatively managed, while 6(60%) required radiological drainage. Wound infection was observed in 9(11.1%) patients, 2(2.4%) required angio-embolisation for postoperative bleeding from branches of left gastric and splenic artery.

The 30-day and 90-day mortality rates were 4(4.9%) and 5(6.2%), respectively. The cause of death was systemic sepsis and multi-organ dysfunction in 4(4.9%) patients, while 1(1.2%) patient developed necrotising wound infection and was re-explored. Abdominal wall debridement and washout was done, but the patient could not survive.

Significantly associated factors for level III and greater complication included intraoperative blood loss >500ml, and more than one co-morbid conditions, and intraoperative blood loss >500ml was significantly associated with 90-day mortality ($p<0.05$). There was no association of 90-day mortality with duration of surgery, BMI and preoperative stage of disease (Tables 3-4).

Discussion

EBTs are relatively infrequent tumours and owing to their surgical complexity, reports on outcomes of surgical resection of EBT are scarce. Postoperative complications in these patients have been reported to be up to 53% due to the aggressive nature of these tumours, requirement of extensive resection, and lymphadenectomy.[10-12] Postoperative complications are known to affect the long-term survival outcomes in patients with other gastrointestinal cancers as a result of immune-mediated responses of the body, malnutrition and delay in adjuvant therapy[11]. However, this mechanism has not been fully explored for EBT. The current study was planned to highlight the postoperative outcomes of EBT which may in future help establish prognostic indices for EBT.

Despite the high rates of morbidity, postoperative mortality rate for EBT has significantly improved in the past few decades. Use of preoperative radiological imaging for surgical planning, biliary drainage, newer and robust cautery and stapler devices, and the provision of neoadjuvant therapy have significantly impacted the overall mortality rate in EBT13. Kuipers et al. reported a 30-day mortality rate of 12% in a cohort of 33 patients undergoing extended resection for advanced GBC.[14] A study on DCC reported 30-day mortality of 4.8% and 90-day mortality of 7.7%.[15] In the current cohort, the 90-day mortality rate was comparable.

Preoperative jaundice has been associated with postoperative morbidity in biliary tumours. A meta-analysis reported higher incidence of surgical site infection in patients operated for malignant obstructive jaundice without preoperative biliary drainage. There was no association between mortality, delayed gastric emptying, anastomosis leak and preoperative biliary drainage.[16] In the current study 58% patients presented with jaundice, and most of them underwent drainage procedures. However biliary drainage was not associated with mortality or postoperative complications in the cohort.

Poor nutritional status, as determined by albumin levels, low BMI or radiological determination of sarcopenia, has often been associated with the development of serious postoperative complications, including anastomotic leak, wound-related complications and prolonged LOS in patients undergoing major abdominal surgery.[17-19] However, its role in biliary tumours is still unclear. Chakedis et al. studied the effects of sarcopenia on postoperative outcomes after biliary tract surgery. Sarcopenia was identified in 35% patients with biliary tumours. The presence of sarcopenia was not associated

with postoperative morbidity, but 30-day mortality was higher in the sarcopenic group, and sarcopenia was also associated with shorter survival after recurrence.[20] Prognostic scores based on sarcopenia are being developed to predict and improve postoperative outcomes and oncological outcomes in various abdominal malignancies, including gastric cancer, colon cancer and pancreatic cancer.[21-24] The need of such prognostic scores for EBT is there to improve the outcomes of patients undergoing resection for EBT.

Anastomosis leak is one of the most devastating complications after hepatopancreatobiliary surgeries as it leads to significant mortality and morbidity, and is also associated with poor quality of life. Anastomotic leak rates of as high as 23% have been reported in the literature and several factors, including surgical technique, patient's nutritional status, extent of disease etc., have been associated with it.[25] Burkhart et al. reported the incidence of hepatico-jejunostomy leak at a high-volume centre, concluding that the leaks were associated with low albumin levels. They managed all leaks conservatively.[26] The current study showed an anastomosis leak rate of 3.7%. Even though univariate analysis failed to show its association with the aforementioned factors, there is still a need to further identify factors responsible for the development of leaks and improve outcomes.

EBTs often require complex surgical resections, including major or minor hepatic resection. Although the current cohort had only three patients who required major hepatic resection, 31 patients had EBL >500ml and 41 required intraoperative transfusion. A meta-analysis reported that EBL resulted in higher rate of postoperative complications in colorectal cancer surgeries.[27] Charalambidies et al. performed a systematic review on colorectal patients, and reported similar results.[28] Though much work has been done to evaluate the association of EBL with postoperative outcomes, there is no consensus in literature regarding this specific domain, and data for EBT surgeries is scarce.

Multiple comorbidities have a negative impact on postoperative course and have been shown to have a role in poor prognosis with decreased overall survival in oncological patients.[29-30] Yu et al. reported that two or more comorbidities were a significant predictor of adverse postoperative outcomes in patients who had undergone gastrectomy (p=0.009).[31] Flynn et al. studied postoperative outcomes in colorectal cancer patients, and concluded that patients with more comorbidities and higher American Society of Anaesthesiologists (ASA) class were more likely to develop complications (p=0.029)[32]. The current study observed a higher number of adverse events in patients with two or more comorbidities, but there was no significant association of postoperative complications with ASA class. Additional studies may help establish the prognostic role of comorbidities in patients with EBTs.

The current study has limitations since hepatobiliary surgery is routinely performed at very few centres, and the number of EBT cases are fewer than other oncological surgery cases. The current study has a retrospective design and the sample was raised form a single, non-specialised centre. owing to the retrospective design, missing data and selection bias also could not be ruled out. Oncological outcomes were not described due to a large number of cases that had been lost to follow-up.

Conclusion

Data from a low-volume centre presented results comparable with international data. Further data and long-term follow-up are warranted to improve the overall morbidity.

Disclaimer: None.

Conflict of Interest: None.

Source of Funding: None.

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AUTHOR'S CONTRIBUTION:

AAK: Concept, data collection, analysis, interpretation, writing, final approval and agreement to be accountable for all aspects of the work.
MRK: Concept, data interpretation, writing, final approval and agreement to be accountable for all aspects of the work.
JS: Data analysis, interpretation, writing, final approval and agreement to be accountable for all aspects of the work.