How to Cite:
Yogesh, Y., & Hansdah, S. C. (2022). Comparing early and delayed repair of common bile duct injury to identify clinical drivers of outcome and morbidity. *International Journal of Health Sciences*, *6*(S6), 894–903. https://doi.org/10.53730/ijhs.v6nS6.9710

Comparing early and delayed repair of common bile duct injury to identify clinical drivers of outcome and morbidity

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***Abstract*---**Background: When it comes to fixing a common bile duct injury (CBDI), center and surgeon experience matter. There is a lack of information on the factors that influence morbidity in relation to repair time in this group. Methods: Patients with CBDI who had surgery at a single facility were retrospectively examined from January 2020 to June 2021. Patient outcomes were compared between those who had surgery soon after injury (before 48 hours) and those who waited longer. The likelihood of readmission was predicted for individuals undergoing delayed repair. Results: In all, 61 people underwent biliary reconstruction surgery. Patient demographics, damage categorization subtype, incidence of vasculobiliar injury (VBI), hospital length of stay, 30-day readmission rate, and 90-day death rate were not significantly different between the early repair and delayed repair groups.Delaying repairs in patients with VBI or those who have had several endoscopic operations before their repairs enhance their risk of readmission. Using these factors, a predictive model was built. Conclusion: The results for patients receiving early or delayed CBDI repair are comparable when the care is provided by a tertiary hepatopancreatobiliary facility. Evidence-based consensus recommendations for the assessment and treatment of CBDI may assist to determine what variables contribute to morbidity and what criteria may be used to predict clinical outcomes in this group.

***Keywords*---**Comparing, delayed repair, injury, clinical drivers, morbidity.

Introduction

Damage to the extrahepatic biliary tree after cholecystectomy has been widely documented. Despite new research demonstrating a falling incidence of CBDI after laparoscopic cholecystectomy, patients and surgeons continue to worry about the risk of CBDI [1,2]. Complications, such as inflammation and the need for open cholecystectomy, still arise after laparoscopic cholecystectomy, despite the fact that studies have identified patient- and surgeon-related characteristics correlated with CBDI.[3-7] A portion of this study was presented at the 2016 Congress of the International Hepato-Pancreato-Biliary Association (IHPBA) in Sao Paulo, Brazil. Approximately one-third of all instances of CBDI are missed for many days or weeks after the first injury, and may not be recognized until the index operation[8,9].

There is now a standardized method for describing biliary injuries thanks to the development of the Strasberg-Bismuth injury categorization system. Vasculobiliary injury (VBI) has been described using a rising variety of words, such as VBI5[10] and severe VBI[11], but no injury description model indicates when damage should be treated. Reconstitution of bilioenteric flow is the final treatment for biliary injury, although it may need further surgical or endoscopic procedures to diagnose the damage, treat acute intra-abdominal processes such biliary peritonitis, and treat patients who have experienced the injury. It has been discovered that the negative effects on patients' quality of life (QOL) extend well beyond the acute injury and treatment phases, and that the costs of healthcare and the risks of complications increase with each subsequent surgery.[12,13] Repair of CBDI is discussed, both immediately after injury and afterwards. Since there is no established protocol for determining when to do a repair, doctors must weigh the likelihood of success and the patient's safety when deciding whether to perform the treatment immediately or wait. Quality of life for patients and effective use of healthcare resources should be taken into account if equal technical and morbidity results can be attained.

Since cholecystectomy is done so often across the globe, even a minor prevalence of CBDI might result in a significant financial and clinical burden. Previous research on CBDI has shown various elements that contribute to effective recovery. Multidisciplinary perioperative care from a specialist facility run by a skilled hepatopancreatobiliary (HPB) surgeon is one of them.[14–16] Carolinas Medical Facility (CMC) acts as the primary hepatopancreaticobiliary (HPB) referral center for a 48-hospital healthcare system covering four states in the southern United States. The purpose of this research is to review CMC's history of CBDI repairs and to compare the results of these procedures in patients who had either immediate or delayed CBDI repairs.

Methods

The use of previously collected data was authorized by an Institutional Review Board (IRB) of MGM Medical College and Hospital, Jamshedpur. Patients diagnosed with CDBI at a single institution between January 2020 and June 2021 were identified using a database search using International Classification of Diseases (ICD)-9 codes. To ensure that all patients included in the analysis had

received treatment for CBDI, we first eliminated duplicate data before reviewing each individual's chart. Each of the five available HPB surgeons handled each and every operation. Records of past patients were put into a protected database hosted on the internet and in accordance with HIPAA regulations. Patient characteristics, duration since index operation, operative findings (such as injury classification and procedural factors), and postoperative outcomes (30-day readmission and 90-day death) were documented. Prior to and after a definitive repair, the number of times radiographic and endoscopic biliary instrumentation were performed was documented. The Strasberg-Bismuth technique was used to report the CBDI type. 2,9 Radiological imaging and intraoperative ultra- sound (IOUS) results depicting hepatic vascular flow were examined for the existence of VBI. IOUS was used to evaluate for vascular damage in patients undergoing intraoperative CBDI repairs, whereas triphasic CT imaging of the liver was used to evaluate patients who were transferred immediately after a suspicion of injury or who had a repair at a later time.

The diagnostic imaging process was preceded by a surgical investigation of any patient who was hemodynamically unstable upon admission. Definitive biliary repair or reconstruction was performed either immediately after the index surgery (acute) or later (delayed) than 48 hours. Medians, reaches, counts, and rates were each used to illustrate the continuous and exhaustive data. We conducted the Wilcoxon rank-sum test for continuous variables and the Fisher's exact test for discrete ones. At the P 0.05 level, all of the findings were considered to be very significant. All empirical evaluations were performed in SPSS version 13. The cohort of patients who underwent delayed repair was divided into subgroups based on whether they were readmitted within 30 days using univariate analysis to determine the effect of defer on co-morbidities, injury types, and readmission. Patients' socioeconomic status, injury subtype, presence of vascular injury, ongoing circumstances, medications, intraoperative nuances of the biliary redoing an operation, number of supportive endoscopic retrograde cholangiopancreatography (ERCP) frameworks >1, presence of VBI, requirement for percutaneous transhepatic cholangiography (PTC) or transabdominal channel, and length of hospital stay were analysed for correlation. It was generally agreed that p-values below 0.25 were statistically significant.A multiple logistic regression model was built using input from the univariate analysis. Stepwise backward elimination and the Homer–Lemeshow test statistic were employed to further evaluate the model's goodness-of-fit. Both tests required the P-value to be less than 0.10.

The 30-day readmission independent variable coefficient and the overall model coefficient were used to formulate a predictive technique. To assess the model's prediction accuracy, the likelihood of readmission within 30 days was calculated for each individual record and compared to the actual number of readmissions during that time frame. We produced Brier scores and receiver operating characteristic (ROC) curves to assess the model's overall predictive skills based on the anticipated chance of readmission for each participant. Using the final logistic regression model, a readmission score was developed. We divided the ERCP variable into two groups, one for patients who had one operation and another for those who had more than two. VBI and ERCP category ORs were applied, rounded

down to the next negative integer.AUC >0.70 was used to denote a realistically viable model when evaluating these values using ROC.[17–19]

Results

The CBDI of 81 individuals was assessed during the research period. Twenty patients were deemed ineligible for inclusion since they had already been successfully treated with ERCP and did not need any further biliary surgery. During a laparoscopic operation, iatrogenic CBDI was detected, resulting in the need for an open cholecystectomy and the hospitalization of the patient who had Roux-en-Y hepaticojejunostomy to rectify the condition. Two patients having laparoscopic cholecystectomy experienced cystic duct stump leaks (Strasberg-Bismuth type A CBDI), requiring hepatectomy with portal lymphadenectomy and bile duct resection. In 4 of the 17 patients who had definitive ERCP for biliary peritonitis, laparoscopic abdominal washout and drain installation were necessary for effective treatment. During the research period, 201 patients were treated with ERCP and stenting alone; they did not undergo surgical biliary reconstruction.A total of 260 patients received CBDI treatment throughout the study period, with 201 of those patients requiring just endoscopic intervention to achieve a favorable outcome. The majority of victims sustained Strasberg-Bismuth Type A and D wounds.

Within the surgical group of 60 patients, CBDI was repaired on the spot in 4 of cases after consultation with an HPB surgeon during surgery. As many as 20 more patients were treated at CMC for their injuries within 48 hours of arrival. 29 patients had their injuries treated within two days. Delayed repair was performed on the remaining 35 patients. On arrival from other facilities, 7 of the 61 cases of CBDI that were surgically treated needed immediate abdominal exploration due to bleeding or infection. In four patients with VBI, early repair was performed during second-look treatment following initial assessment for hemostasis management or reconstruction of the common hepatic artery and portal vein. Other VBI patients (n = 8) were treated with delayed repair. Table 1 displays the characteristics and results of early and delayed CBDI surgical repair procedures that were done throughout the research period. Cholecystectomy was the primary initial surgical objective that resulted in complications for the majority of patients. When comparing patients who had CBDI repaired immediately vs those who waited, no discernible changes were seen in demographics or health outcomes. One month following surgery, the body mass index (BMI) of both the early and delayed groups decreased from preoperative levels (P = 0.122). We performed a retrospective study, using pre- and post-operative blood albumin levels as surrogates for nutritional status. There were no notable differences between the two groups on any other clinical or surgical outcomes.

VBI (OR 4.2, P = 0.10) and every extra preoperative ERCP above that utilized for diagnosis of CBDI were associated with an increased risk of 30-day readmission following the final biliary reconstruction among the 34 patients with delayed repair. With these variables in mind, we were able to create a model that could predict whether or not a patient would need to be readmitted within 30 days if CBDI repair was delayed. Due to the absence of VBI and the single diagnostic ERCP conducted prior to surgery, these patients had a 50/50 chance of being

readmitted. Patients without VBI who had had several ERCPs prior to surgery had a predicted readmission rate of 72 %. It was projected that 85 % of patients with VBI who required several ERCPs prior to repair would be readmitted. The area under the receiver operating characteristic curve for the readmission model was 0.77 (P = 0.00), and the Brier score was 0.47 (where higher values indicate stronger ability to foresee average probability of recurrence across a dataset) (higher scores indicate better ability to predict an outcome at the level of an individual patient).

Table 1
Operative features and results of common bile duct damage surgical repair treatments at a single center2020–2021 (n = 61)

Characteristic or outcome	Immediate and early repair (<48h from injury)	Delayed repair (>48h from injury)	*P* Value
Patients,No.	25	36	0.41
Men,No.	11	14	0.61
Age,median,y	57	51(24–80)	0.30
BMI, kg/m^2,median(range)	23	26.6(15.8–44.9)	0.773
Etiology,No.			
Cholecystectomy	14	27	0.42
Non-biliaryabdominal Procedures	8	7	0.33
Abdominaltrauma	1	0	0.11
Hospitallengthofstay, median,days(range)	6	7	0.43
30-dayreadmission,No.	4	4	0.64
90-daymortality,No.	4	0	0.07
IntraoperativeRepair,No.	5	–	–
ASAclassification≥3,No.	14	22	0.95
EBL,median,mL(range)	96	254	0.81
Timetorepair,median,days (range)	1	50	0.77
Vasculobiliaryinjury,No.	5	7	0.24
Strasburg-Bismuth classification,No.			
A	0	2	0.21
B	0	1	0.33
C	3	4	0.87
D	2	2	0.79
E1	7	3	0.05
E2	7	9	0.88
E3	4	7	0.45
E4	2	4	0.45
E5	0	1	0.23
X[a]	2	1	0.11

Discussion

This article describes the surgical treatment of CBDI at a specific institution during the years 2008 and 2015. CMC institutional practices stress comprehensive clinical, radiographic, and endoscopic screening to choose candidates for early repair and to manage acute issues developing in the temporization of CBDI requiring delayed surgery. During the study period, 61 individuals required surgical repair, whereas 199 patients responded well to endoscopy and stenting alone. The majority of patients whose injuries were treated endoscopically suffered from Strasberg-Bismuth types A and D.199/260 (76.5% of the total) CBDI were treated endoscopically, which is higher than the 57.7%-20%-62.25% success rates reported by comparable studies. [20]

The existence of VBI and the fact that the first HPB assessment did not take place until several days after the index procedure both contributed to the need of postponing the repair. Although late presentation may be ascribed in part to the geographical breadth of the referral zone, around 35% of patients who had delayed repair had to wait because of delays in damage discovery.If 8 ERCPs were conducted, including stenting, before a surgical referral was made, then a delay in diagnosis of 18- 25 days is not regarded to have occurred. We chose 48 hours as the cutoff between early and delayed repair since, beyond that period, very few repairs were being performed before 4–6 weeks after damage. Due to the fragmentation of time in this retrospective investigation, 48 h was selected for analysis even though early healing has been reported and assumed to be feasible up to 7 days[8] or 5 days[21] after damage.

The literature suggests that around 25% of individuals with CBDI also have concurrent vascular damage.[10,11,14] A liver transplant may be required in the case of severe vasculobiliary damage. While arterial injury may be a cause to delay treatment owing to worry about biliary or bilioenteric anastomotic structure, these issues are discussed elsewhere.[8,10,11,22,23,24]In the present investigation, three patients had tangential hepatic vascular injuries that required intervention to prevent additional bleeding, and one patient experienced a severe VBI that necessitated the removal of a segment of portal vein and an appropriate hepatic artery. Due to the high risk of hepatic infarction and the lack of other treatment options, this patient underwent rapid venous allograft repair of the hepatic vasculature within hours of injury. Hepaticojejunostomy was performed as a second-look procedure after the patency of the arterial and venous systems was confirmed. Approximately 10% of VBI11 cases may be classed as severe VBI, whereas only 8.3% of CMC cases are considered severe. When primary healing is not possible because of poor tissue quality, the damage location, or segmental biliary resections, early hepaticojejunostomy is done. Due to the risk of two anastomoses in an infected or inflammatory area, this is not done following washout for biliary peritonitis.

It was expected that indicators of injury severity, such as traumatic brain injury (TBI) or numerous endobronchoscopic procedures (ERCPs), would have an impact on clinically meaningful outcomes like readmission. However, the difficulty in developing a reliable prediction model is exacerbated by the low 30-day readmission rate after reconstruction (ROC 0.682). Surgeons will be better able to

advise patients and families about the potential of readmission based on pre-reconstruction or perioperative variables if more patients undergo delayed repair and the model is improved. Individualizing the discussion of expectations and adapting perioperative routes or post-discharge planning for patients at risk for certain problems is made possible by risk identification.

Public perioperative prognostic models for Roux-en-Y hepaticojejunostomy exist, such as the American College of Surgeons National Surgical Quality Improvement Program® (ACS NSQIP®) Surgical Risk Calculator; however, these models do not account for illness-specific natural determinants of grimness, such as vascular bypass graft infection (VBI), the need for pre-meditation PTC or delayed transabdominal channel, or dietary deficiencies. [25,26,27,28] As a result, we developed cutting-edge prediction algorithms for a particular high-throughput process routinely carried out at CMC. Although there are consensus recommendations outlining perioperative protocols for a variety of HPB operations [29-33] not including biliary reconstruction, there is currently no evidence-based practice approach to enhance perioperative treatment. Delay in reconstructive surgery is an elective procedure, so it may be possible to incorporate evidence-based preoperative patient optimization and perioperative care, and it would also make it easier to collect standardized data for the purpose of establishing disease process-specific prediction platforms. Since there is not yet a biliary-specific Enhanced Recovery After Surgery (ERAS) pathway, patients at CMC are enrolled in the program for hepatectomy instead.

The retrospective character of the research and the relatively small sample size are limitations. For this reason, type II error cannot be ruled out. Bilioenteric anastomotic stricture is one issue that may be difficult to identify over the long run due to the scope of the catchment region. Because of the focus on surgical treatment of CBDI in this investigation, endoscopic management of Strasberg-Bismuth types A and D injuries at facilities farther afield may be overlooked. Evaluation of quality of life is also missing from this retrospective research. When comparing the median percentage change in blood albumin levels before and after surgery and at the 1-month follow-up, there was a significant difference between the groups. Intestinalization of bile flow for nutrient absorption may enhance nutritional status. Conclusive data may be gleaned via looking into the future and analysing nutritional evaluations. Although both laparoscopic and robotic CBDI repair were carried out, the series size was insufficient to draw any firm conclusions about whether or not these techniques improved outcomes compared to more invasive open surgery. Quality-of-life (QOL) evaluation for endoscopic treatment, open repair, and minimally invasive repair are all promising avenues for further study. Prospective data collection is proposed as a means to standardize the pre- and post-operative care of patients undergoing bilioenteric repair, bolster current prediction platforms, and even find injury-specific predictors of morbidity.

Conclusion

These findings collectively support the idea that timely and delayed CBDI fixes yield the same perioperative clinical outcomes with the help of skilled specialists and a well-honed focus on appraisal and the board of CBDI; In addition, patients

were classified at the 48-hour mark for early fixation based on the study of this group (Fig. 2). There has been prior recognition of the value of having a trained HPB expert examine and manage wounds. 14-16,28 Early and delayed CBDI repair had comparable perioperative clinical effects, however this study did not examine the hypothesis that QOL and total cost of care for CBDI may improve if early treatment is implemented in well selected individuals.In addition, this would facilitate the quick referral of HPB patients for examination and treatment.More research is needed to determine what factors contribute to worse outcomes for individuals undergoing CBDI repair.

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