

Safety and Efficacy of ERCP in Cirrhotic Patients with Obstructive Jaundice

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Abstract

Background: Endoscopic retrograde cholangiopancreatography (ERCP) is a primary treatment option for various pancreatobiliary disorders. However, there is a lack of prospective studies on the safety of ERCP in cirrhotic patients, with conflicting results. This study aims to compare the outcomes of ERCP in cirrhotic patients with those in non-cirrhotic patients. **Methods:** In this prospective study, 54 cirrhotic patients undergoing therapeutic ERCP were compared to 65 non-cirrhotic patients in a control group. Basic pre-endoscopic and interventional data, as well as 30-day follow-up data, were collected and analyzed. Patients were assessed for the development of complications and the success of the procedure. **Results:** There was no significant difference between cirrhotic and non-cirrhotic patients in terms of overall complication rates (11.1% vs 12.3%, $P=0.84$) and individual complications. Clinical success was slightly higher in the non-cirrhotic group, but the difference was not statistically significant (87.7% vs 79.6%, $P=0.478$). Independent predictors of mortality among our patients included a history of variceal bleeding, splenomegaly, ascites, and post-ERCP cholangitis. The cirrhotic group experienced a significant delay in the improvement of serum bilirubin levels. **Conclusion:** ERCP is considered safe and effective in cirrhotic patients, with clinical success rates comparable to non-cirrhotic patients. However, in cirrhotic patients with advanced liver disease, there may be a delay in the improvement of serum bilirubin levels.

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) has become one of the most commonly performed endoscopic procedures. It has evolved from a diagnostic procedure to an almost therapeutic procedure and is indicated in many pancreatobiliary diseases, including choledocholithiasis, acute cholangitis, biliary strictures and chronic pancreatitis¹. Cirrhotic patients are susceptible to various conditions that may require ERCP, such as biliary stricture and biliary stones. Gallstones and choledocholithiasis have a higher incidence in cirrhotic patients compared to the general population, potentially leading to the need for frequent ERCP procedures. Gallstones are present in up to one-third of patients with liver cirrhosis². ERCP can be a high-risk and challenging procedure when performed on cirrhotic patients³. ERCP carries risks of specific adverse events, such as post-ERCP pancreatitis (PEP), hemorrhage, infection, and perforation.

Moreover, individuals with liver cirrhosis are believed to be at a greater risk of experiencing these complications due to the impaired synthetic function of the liver, portal hypertension, ascites, varices, and coagulopathy¹. Surgery may not always be an option for pancreatobiliary disorders in patients with cirrhosis due to the high rates of morbidity and mortality associated with underlying liver disease. As a general guideline, minimally invasive approaches, such as ERCP, are preferred for these patients. Despite the acknowledged high risk of post-ERCP adverse events in patients with liver cirrhosis, there is a lack of literature and conflicting results regarding the outcomes of ERCP procedures in cirrhotic patients. Prospective studies on this issue are limited⁴. Therefore, this study aims to evaluate the outcomes of ERCP, including adverse effects and success rates, in cirrhotic patients compared to a non-cirrhotic group.

Patient and Methods

This was a prospective cohort comparative study conducted at the Specialized Medical Hospital, Mansoura University, Egypt, a tertiary hospital, on patients attending our advanced endoscopy unit for therapeutic ERCP from 2019 to 2022. Patients were divided into two groups: *) Case group: Included 54 consecutive patients with an established diagnosis of cirrhosis. They were further subdivided according to the severity of cirrhosis into compensated (34 patients, 63%) and decompensated (20 patients, 37%) cirrhosis subgroups. *) Control group: Included 65 consecutive patients without cirrhosis. Subjects of our study were randomly selected to avoid selection bias;(ie, 1st consecutive 54 cirrhotic patients and 1st consecutive 65 non-cirrhotic patients were selected. After completion of all cases of the study, we did not find statistically significant difference in the indications of ERCP between both groups.

Inclusion criteria

Patients above 18 years with established diagnosis of obstructive jaundice.

Exclusion criteria

Patients under 18 years old, pregnant women, cases of hepatocellular carcinoma (HCC), patients with altered anatomy (such as Billroth II or Roux-en-Y gastric bypass) that hinder access to the papilla, and cases post-liver transplantation.

Preoperative patient assessment

All patients underwent a comprehensive evaluation including a detailed medical history, physical examination, and laboratory tests included complete blood count (CBC), serum

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levels of total and direct bilirubin, ALT, AST, alkaline phosphatase, creatinine, albumin, and INR. Abdominal ultrasound was initially performed to assess for biliary obstruction, with further imaging modalities such as MRCP and/or triphasic CT abdomen utilized as necessary to determine the underlying cause of the obstruction.

Definitions

Cirrhosis

Cirrhosis was diagnosed based on the patient's medical history, clinical examination, and ultrasonographic features such as irregular borders, coarse echo-pattern, enlarged caudate lobe, splenomegaly, dilated portal vein, or ascites. In cases where a histopathology report was available, liver biopsy was used to confirm the diagnosis.

Decompensated cirrhosis

Decompensated cirrhosis was defined according to Baveno VII consensus criteria (ascites, encephalopathy or variceal haemorrhage)⁵.

Procedure

Patients with an international normalized ratio (INR) >1.5 were administered vitamin K and/or fresh-frozen plasma. Patients with a platelet count <50,000/mm³ received platelet transfusion before the procedure. ERCP was performed using a side-view duodenoscope, (the PENTAX-ED3490TK). All patients received general anesthesia administered by anesthesiologists. Intraendoscopic interventions such as sphincterotomy, precut, balloon dilatation, and stent placement were documented. If accidental cannulation of the main pancreatic duct occurred more than once, a prophylactic pancreatic duct stent was inserted, and rectal indomethacin suppositories were administered. All intra-procedural details were recorded, including sphincterotomy, precut, sphincteroplasty, stone extraction, balloon dilatation, and stent insertion.

Follow up

- *) All patients were admitted for at least 24 hours post-procedure for close monitoring and then followed up for 30 days post-procedure to assess success and monitor for complications.
- *) Serum bilirubin and liver function tests were conducted at 2-week and 1-month intervals after the procedure.
- *) The primary outcome was the development of adverse events (such as PEP, cholangitis, bleeding, and perforation) and mortality. The secondary outcome was the technical and clinical success of the procedure.

ERCP Complications

Post-ERCP pancreatitis was defined and graded according to the revised Atlanta classification of acute pancreatitis⁶. Post ERCP Bleeding, cholangitis and perforation were defined and graded according to ASGE consensus guidelines for grading of severity of post-ERCP complications⁷. Perforation type was further classified according to Stapfer, et al⁸.

Definition of success

Technical success was defined as successful deep biliary cannulation and achieving the goal of ERCP, such as the removal of biliary stones or insertion of a biliary stent with secured biliary drainage at the end of the procedure.

Clinical success

Decrease in total bilirubin level to <3 at 30 days, or no increase in the total bilirubin level over 1 mg/dl within 2 or 4 weeks if the pretreatment value was <3. In the case of malignant hilar obstruction, clinical success was defined as a decrease in the total bilirubin level to ≤30% of the pretreatment value within 2 weeks or to ≤50% within 4 weeks⁹.

Ethical Statement

The study protocol was approved by the ethical committee at the Faculty of Medicine, Mansoura University (MD.19.06.198) and adhered to the Declaration of Helsinki 2013. Written informed consent was obtained from participants ensuring confidentiality. All authors had access to and approved the study data and final manuscript.

Statistical analysis and data interpretation

Data analysis was conducted using SPSS software, version 25 (SPSS Inc., PASW Statistics for Windows version 25, Chicago: SPSS Inc.). Qualitative data were presented as numbers and percentages. Quantitative data were reported as median (minimum and maximum) for non-normally distributed data and mean ± standard deviation for normally distributed data after testing for normality using the Kolmogorov-Smirnov test. The significance level was set at ≤0.05. Chi-square, Fisher's exact test, and Monte Carlo tests were employed to compare qualitative data between groups as appropriate. The Mann-Whitney U test was used to compare two studied groups for non-normally distributed data. The Wilcoxon signed-rank test and Friedman test were utilized to compare more than two studied periods. The student's t-test was applied to compare two independent groups for normally distributed data. Binary logistic regression was used to evaluate the impact of a combination of more than two independent variables on a dichotomous outcome using stepwise/forward Wald/Enter techniques.

Results

A total of 119 patients were included in the study, with 54 (46%) diagnosed with cirrhosis and 65 (54%) without cirrhosis. Among the cirrhotic patients, 44 (81.5%) were male and 10 (18.5%) were female, with a mean age of 65±9.80 years. There were no statistically significant differences between the two groups in terms of basic demographic data, except for a higher proportion of males in the cirrhotic group, **table 1**. **Figure 1** summarizes the causes of obstructive jaundice. It was observed that the most common cause of obstructive jaundice in our study population was calculi obstruction (70.4% in cirrhotics vs. 53.8% in non-cirrhotics), followed by pancreatic head cancer (11.1% in cirrhotics vs. 27.7% in non-cirrhotics). Other causes included cholangiocarcinoma, benign stricture, hepatic duct stone, peri-ampullary carcinoma, and malignant lymph node. These causes were evenly distributed between the two groups with no significant differences. **Table 2** displays the intervention procedures performed in the two study groups. There was no statistically significant difference between the groups in terms of intra-procedural interventions. Sphincterotomy was performed in 70.4% of cirrhotic patients compared to 64.6% of non-cirrhotic patients (P=0.5), precut in 13% vs. 16.9% (P=0.55), and sphincteroplasty in 13% vs. 15.4% (P=0.7). Other interventions, such as stent insertion and the type of stent used did not show any significant differences.

Adverse events

Overall, complications developed in six cirrhotic patients (11.1%) compared to eight non-cirrhotic patients (12.3%), which was statistically insignificant (P=0.84). The incidence of individual complications in both groups was as follows: post-endoscopic retrograde cholangiopancreatography (PEP) (0% vs 4.6%, P=0.250), bleeding (3.7% vs 3.1%, P=0.375), cholangitis (7.4% vs 3.1%, P=0.4), and perforation (0% vs 1.5%), all of which were non-significant. Although mortality was relatively higher among the cirrhotic group (11.1% vs

4.6%; $P=0.182$), it did not reach statistical significance **Table 3**. In subgroup analysis, we did not find a significant difference in complications between compensated and decompensated cirrhotic patients. Cholangitis occurred in 8.8% of patients with compensated cirrhosis compared to 5% in decompensated cirrhosis. Bleeding occurred in 2.9% of compensated cirrhotic patients versus 5% in decompensated cirrhotic patients, **table 4**. Regarding ERCP success, there was no significant difference in technical and clinical

success between both groups. However, clinical success was slightly higher among the non-cirrhotic group (87.7% vs. 79.6%, $p=0.23$), **table 5**. There was a significant delay in the improvement of serum bilirubin in the cirrhotic group, **table 6**. In the binary logistic regression analysis, the independent predictors of mortality among our patients were a history of variceal bleeding, presence of splenomegaly, ascites, and the occurrence of post-ERCP cholangitis, **table 7**.

Table 1: Socio-demographic characteristics of the studied groups

| | Non cirrhotic n=65 | Cirrhotic n=54 | P value |
|--------------|-----------------------|-------------------|---------|
| Age/years | 60.46±16.11 | 65±9.80 | 0.07 |
| Sex | | | |
| ▪ Male | 34 (52.3%) | 44 (81.5%) | 0.001 |
| ▪ Female | 31(47.7%) | 10 (18.5%) | |
| Smoking | | | |
| ▪ No | 49(75.4%) | 42(77.8%) | 0.850 |
| ▪ Ex-smoker | 4(6.2%) | 4(7.4%) | |
| ▪ Smoker | 12(18.5%) | 8(14.8%) | |
| DM | 12(18.5%) | 14(25.9%) | 0.327 |
| Hypertension | 17(26.2%) | 10(18.5%) | 0.322 |

t: Student t test, MC: Monte Carlo test, χ^2 =Chi-Square test, *statistically significant, parameters described as mean± SD, number (percentage)

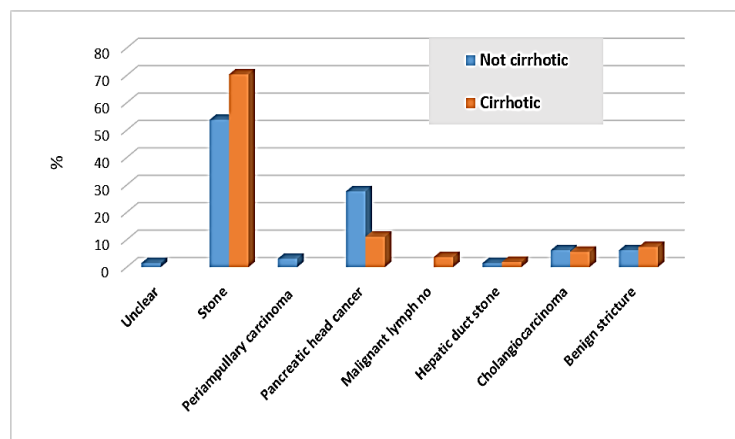


Figure 1: Distribution of the cause of biliary obstruction among studied groups.

Table 2: Comparison of endoscopic interventions procedures between studied groups

| | Non cirrhotic n=65 | Cirrhotic n=54 | test of significance |
|---------------------|-----------------------|-------------------|-----------------------------|
| Sphincterotomy | 42(64.6%) | 38(70.4%) | $\chi^2=0.443$ $P=0.505$ |
| Precut | 11(16.9%) | 7(13.0%) | $\chi^2=0.360$ $P=0.548$ |
| Balloon dilatation | 10(15.4%) | 7(13.0%) | $\chi^2=0.141$ $P=0.707$ |
| CBD Stent | 40(61.5%) | 33(61.1%) | $\chi^2=0.002$ $P=0.962$ |
| Type of CBD stent | | | |
| ▪ No | 25(38.5%) | 21(38.9%) | MC=1.53 $P=0.679$ |
| ▪ Plastic | 29(44.6%) | 25(46.3%) | |
| ▪ Metal | 11(16.9%) | 7(13.0%) | |
| ▪ Plastic and metal | 0 | 1(1.9) | |
| Stone extraction | 29(44.6%) | 24(44.4%) | $\chi^2=0.0$ $P=0.985$ |

| | | | |
|---------------------------------------|---------|---------|---------------------------|
| Accidental pancreatic duct canulation | 3(4.6%) | 5(9.3%) | $\chi^2=2.04$ P=0.154 |
| Pancreatic duct stenting | 2(3.1%) | 5(9.3%) | $\chi^2=1.01$ P=0.314 |
| Reintervention within one month | 3(4.6%) | 4(7.4%) | $\chi^2=0.415$ P=0.519 |
| Interval to reintervention (days) | 3(3-15) | 7(7-7) | Z=0.471 P=0.637 |

Table 3: Comparison of post endoscopic complications between studied groups

| | Non cirrhotic n=65(%) | Cirrhotic n=54(%) | test of significance |
|-----------------------------------|--------------------------|----------------------|--------------------------|
| PEP Total | 3(4.6%) | 0 | FET=2.56 P=0.250 |
| PEP degree | | | |
| ▪ Mild | 2(66.7%) | 0 | |
| ▪ Moderate | 0 | 0 | |
| ▪ Severe | 1(33.3%) | 0 | |
| Bleeding Total | 2(3.1%) | 2(3.7) | FET=0.617 P=0.99 |
| Mild | 1(50%) | | |
| Moderate | 1(50%) | 2(100%) | |
| Cholangitis Total | 2 (3.1%) | 4(7.4%) | MC=2.50 P=0.408 |
| Moderate | 0 | 2(50%) | |
| Severe | 2(100%) | 2(50%) | |
| Perforation (total) | 1(1.5) | 0 | FET=0.838 P=1.0 |
| Mild | 1(100%) | 0 | |
| Total complications | 8(12.3%) | 6(11.1) | $\chi^2=0.04$ p=0.84 |
| Mortality | 3(4.6%) | 6(11.1%) | $\chi^2=1.79$ p=0.182 |
| Time to death Median (min-max) | 7(4-12) | 21.5(6-31) | Z=1.74 P=0.081 |

FET: Fischer exact test

Table 4: Comparison of complications between compensated and decompensated cirrhosis patients

| | Compensated n=34 (63%) | Decompensated n=20(37%) | test of significance |
|---------------------|---------------------------|----------------------------|----------------------------|
| Bleeding(moderate) | 1(2.9%) | 1(5.0%) | FET=0.149 P=0.99 |
| Cholangitis | | | |
| ▪ No | 31(91.2%) | 19(95%) | MC=1.34 P=0.512 |
| ▪ Moderate | 2(5.9%) | 0 | |
| ▪ Severe | 1(2.9%) | 1(5%) | |
| Total complications | 4(11.8) | 2(10%) | FET=0.039 P=1.0 |
| Mortality | 4(11.8%) | 2(10%) | $\chi^2=0.0009$ P=0.976 |

Table 5: Comparison of technical and clinical success between studied groups

| | Non cirrhotic n=65 | Cirrhotic n=54 | test of significance |
|-------------------|-----------------------|-------------------|-------------------------|
| Technical success | 65(100%) | 53(98.1%) | $\chi^2=1.22$ P=0.27 |
| Clinical success | 57 (87.7%) | 43(79.6%) | $\chi^2=1.42$ P=0.23 |

Table 6: Post-endoscopy serum bilirubin level of the studied groups

| | Non cirrhotic n=65 | Cirrhotic n=54 | test of significance |
|----------------------------------|-----------------------|-------------------|----------------------|
| Bilirubin 2 weeks (mg/dl) | 1.95(0.4-24.9) | 3.77(0.6-27.8) | Z=2.54 P=0.01* |
| Bilirubin 1 month (mg/dl) | 1.2(0.4-18.2) | 2.1(0.6-31) | Z=3.76 P<0.001* |

Table 7: Binary logistic regression of predictors of mortality among studied cases

| | β | p value | odds ratio (95% CI) |
|----------------------------------|---------|---------|------------------------|
| Age/years | 0.012 | 0.609 | 1.01(0.966-1.06) |
| Platelets | -0.001 | 0.694 | 0.999(0.992-1.01) |
| INR | 0.829 | 0.479 | 2.29(0.231-22.70) |
| US ascites | | | |
| ▪ <i>No</i> | 1.64 | 0.014* | 1 |
| ▪ <i>Yes</i> | | | 5.17(1.39-19.07) |
| Spleen | | | |
| ▪ <i>Normal</i> | | 0.079 | 1 |
| ▪ <i>Enlarged</i> | 1.77 | 0.029* | 5.91(1.19-29.19) |
| ▪ <i>Splenectomy</i> | 2.05 | 0.123 | 7.75(0.573-104.83) |
| Bilirubin 2 weeks | -0.006 | 0.965 | 0.999(0.763-1.29) |
| Non cirrhotic | 1.28 | 0.069 | 3.59(0.904-14.29) |
| Cirrhotic | | | |
| Hx of encephalopathy | 0.361 | 0.749 | 1.44(0.16-13.07) |
| Hx of EVL | 1.30 | 0.084 | 3.67(0.838-16.11) |
| Hx of variceal bleeding | 1.69 | 0.03* | 5.41(1.17-25.04) |
| Cause of obstruction | | | |
| ▪ <i>Unclear</i> | R | .636 | 1 |
| ▪ <i>Stone</i> | 18.790 | 1.+ | undefined |
| ▪ <i>Periampullary carcinoma</i> | 21.203 | 1.000 | undefined |
| ▪ <i>Pancreatic head cancer</i> | 18.805 | 1.000 | undefined |
| ▪ <i>Malignant lymph no</i> | .000 | 1.000 | undefined |
| ▪ <i>Hepatic duct stone</i> | 21.203 | 1.000 | undefined |
| ▪ <i>Cholangiocarcinoma</i> | 19.411 | 1.000 | undefined |
| ▪ <i>Benign stricture</i> | .000 | 1.000 | undefined |
| Decompensated cirrhosis | 0.023 | 0.977 | 1.02(0.217-4.83) |
| Post ERCP cholangitis | -2.15 | 0.04* | 0.89(0.79-0.99) |
| overall % predicted=90.8% | | | |

Discussion

In this prospective single-center study, we examined the outcomes of ERCP in cirrhotic patients compared to a non-cirrhotic group. The cirrhotic group was further categorized into compensated and decompensated subgroups. Previous studies on ERCP outcomes in cirrhotic patients often used the CTP score to define decompensation, which may be influenced by high bilirubin levels from obstructive jaundice. In our study, we defined decompensation based on the Baveno VII staging of cirrhosis, which considers the presence of variceal bleeding, ascites, or hepatic encephalopathy⁵. There are conflicting results in the literature regarding the incidence of post-ERCP complications in cirrhotic patients, and there is a lack of prospective studies investigating this issue. In our study, we found no significant difference in the incidence of overall complications between cirrhotic and non-cirrhotic groups. Consistent with our findings, some studies have also reported similar results regarding complications in cirrhotic and non-cirrhotic patients. Adler et al. noted that

the overall incidence of adverse events in patients with cirrhosis was comparable to that in the general population undergoing ERCP¹⁰. Similarly, Peiseler et al. observed that the incidence of adverse events following ERCP was 4.4% in cirrhotic patients compared to 7% in non-cirrhotic patients, which was not statistically significant¹¹. On the other hand, our results differ from that of other studies that found significantly higher incidence of post ERCP complications in cirrhotics such as Navaneethan et al¹. Leal et al.¹², and Tarar et al¹³. In terms of post-endoscopic PEP, there was no significant difference between the cirrhotic and non-cirrhotic groups, with rates of 0% and 4.6% respectively. This aligns with the findings of Li et al¹⁴. and Macías-Rodríguez et al.¹⁵. On the contrary, our results contrast with those of Inamdhar et al.¹⁶ and Navaneethan et al¹, who reported a significantly higher incidence of PEP in cirrhotic patients compared to non-cirrhotic patients. This discrepancy may be attributed to the preventive measures implemented during the procedures,

such as the placement of a pancreatic duct stent and the use of rectal indomethacin in cases of inadvertent pancreatic duct cannulation. The occurrence of PEP exclusively in the non-cirrhotic group could be explained by the higher proportion of female patients in this group compared to the cirrhotic group (47.7% versus 18.5% respectively), which is recognized as a risk factor for PEP¹⁷. The discrepancy in results could be attributed to differences in the study population and the retrospective nature of the other studies. Pancreatitis was mild in 2 cases and severe in one case, which led to systemic and local complications requiring ICU admission, but there were no fatalities. Regarding post-ERCP bleeding, there was no significant difference between cirrhotic and non-cirrhotic groups (3.7% versus 3.1% respectively; $P=0.99$). This is consistent with the findings of Peiseler et al.¹¹ and Bernshteyn et al.¹⁸, who also did not observe a significant difference between the two patient groups. In contrast, studies by Gill et al.¹⁹ and Leal et al.¹² reported a significantly higher incidence of bleeding in cirrhotic patients compared to non-cirrhotic patients. This discrepancy may be attributed to the proper pre-procedural preparation of cases, including correction of coagulopathy before the procedure, as well as immediate management of any intraprocedural bleeding with techniques such as balloon compression or APC. Additionally, the higher proportion of decompensated cirrhotic patients (Child B and C patients) in previous studies could account for this difference. The cases of bleeding in our study ranged from mild to moderate. One case was managed conservatively with spontaneous cessation of bleeding, while the other three cases required blood transfusion and a second look endoscopy. No interventional radiology or surgical intervention was necessary in any of the cases. Cholangitis was observed in 7.4% of cirrhotic patients, slightly higher than the incidence in non-cirrhotic patients (3%). The increased occurrence of cholangitis among cirrhotic individuals in our study may be attributed to the higher prevalence of proximal obstructions (hilar and intraductal obstruction) in the cirrhotic group, which is a known risk factor for incomplete biliary drainage and subsequent cholangitis²⁰. Cirrhotic patients are also known to have a heightened susceptibility to infections due to their immunocompromised state, predisposing them to spontaneous bacterial infections, hospital-acquired infections, and infections from uncommon pathogens²¹. Perforation is a serious complication of ERCP and endoscopic sphincterotomy. Recent studies have reported a low incidence of ERCP-associated perforations, as low as 0.39%. However, the mortality rate associated with these perforations can be as high as 7.8%²². In this study, we encountered only one case of non-cirrhotic perforation (0.8%), which is consistent with findings from previous studies. The perforation was a minor bile duct injury (Stapfer type III) that occurred during instrumentation and was successfully managed by inserting a plastic stent without any additional complications. In subgroup analysis, no significant difference was found in post-ERCP complications between compensated and decompensated cirrhotic patients. Data on the association of ERCP adverse events with Child-Turcotte-Pugh (CTP) class or degree of hepatic decompensation are inconsistent. Some studies have shown a higher prevalence of adverse effects in decompensated cirrhotic patients, with rates being higher in Child class C patients compared to those in Child class B and A^{10,23}. The bleeding

rate was not significantly different between compensated and decompensated patients, which contrasts with previous studies that found a higher incidence of bleeding in patients with Child class C compared to those with Child class A and B^{14,24}. This discrepancy may be attributed to the prophylactic measures taken before the procedure and the use of limited sphincterotomy (with a small incision) combined with sphincteroplasty in decompensated cirrhotic patients, which helped reduce the rate of bleeding. The 30-day mortality rate among our patients was higher in the cirrhotic group but did not reach statistical significance (11.5% in cirrhotics versus 4.6% in non-cirrhotics; $P=0.18$). This result is consistent with the findings of Prat et al. (12.5%)²⁵ and a more recent study by Bernshteyn et al.¹⁸, which reported a 30-day mortality rate of 13.89% among cirrhotic patients. The mortality rate in our study is slightly higher than that reported by Jagtap et al. (8.5%)²³ and Solanki et al., who also found significantly higher mortality in cirrhotic patients compared to non-cirrhotics (4.5% versus 1.4%)²⁶. This difference may be due to the heterogeneity of the study populations and the nature of the procedures. For instance, in Solanki et al.'s study, ERCP was performed for both diagnostic and therapeutic reasons, whereas in our study, ERCP was solely for therapeutic purposes, leading to more interventional complications. Causes of mortality among our patients were either direct ERCP related or other. The direct ERCP related causes were sepsis due to post ERCP cholangitis (2 cirrhotic and 2 non cirrhotic cases). Other causes included liver cirrhosis complications as hepatic encephalopathy (3 cases), other infections (pneumonia in 1 cirrhotic case) or progression of the original disease (pancreatic head cancer) in one non cirrhotic case. Despite the minimal difference in mortality rates between the two groups, we conducted a multivariable analysis to identify any factors contributing to mortality. Our analysis revealed that the independent predictors of mortality among our patients included a history of variceal bleeding, splenomegaly, ascites, and the occurrence of post-ERCP cholangitis. Previous studies have explored the risk factors for mortality following ERCP in cirrhotic patients. Jagtap et al.²³ identified the presence of cholangitis at admission as the sole independent risk factor for mortality in cirrhotic patients undergoing ERCP. In contrast, our study found that post-ERCP cholangitis was among the independent predictors of mortality in our patient population. Solanki et al. analyzed post-ERCP mortality in a group of cirrhotic patients compared to a non-cirrhotic control group. They found that predictors of mortality included the development of post-ERCP complications, older age (>85 years), and the presence of associated comorbidities²⁶. This aligns with our results regarding the association of post-ERCP cholangitis with mortality. However, we did not find a significant association between age and mortality in our study. This may be explained by the fact that the mean age of our entire study population was already high. Clinical success rates were higher in non-cirrhotic patients compared to cirrhotic patients (87.7% versus 79.6%, respectively), although the difference was not statistically significant. Additionally, clinical success was slightly higher in compensated cirrhotic patients compared to decompensated cirrhotic patients, but this difference was also not statistically significant. Our findings contrast with those of other studies that reported significantly higher clinical success rates in non-cirrhotic

patients compared to cirrhotic patients^{12,27}. This disparity in results could be attributed to variations in the indications for ERCP among the study populations, the presence of comorbidities, and the varying degrees of cirrhosis across different studies. Interestingly, we observed a significant delay in the improvement of serum bilirubin levels in the cirrhotic group. The mean serum bilirubin levels at 2 weeks were significantly higher in the cirrhotic group (3.7% vs 1.95%) and remained elevated at 30 days (2.1% vs 1.2%). This indicates a slower recovery of serum bilirubin in cirrhotic patients compared to non-cirrhotics, highlighting impaired excretory function in cirrhotic patients. One of the main limitations of this study is the small sample size and the fact that it was conducted at a single center. However, a significant aspect of our study is its prospective design, as many previous studies on this topic have been retrospective.

Conclusion

ERCP is considered safe and effective in cirrhotic patients, with clinical success rates comparable to non-cirrhotic patients. However, in cirrhotic patients with advanced liver disease, there may be a delay in the improvement of serum bilirubin levels following the procedure. It is important to note that this delay should not be viewed as a failure of the ERCP procedure.

Abbreviations

ALT: Alanine aminotransferase
AST: Aspartate aminotransferase
CBD: common bile duct
ERCP: Endoscopic retrograde cholangiopancreatography
EVL: Endoscopic variceal ligation
MRCP: magnetic resonance cholangiopancreatography
PEP: post-ERCP pancreatitis
FCSEMS: Fully-covered self-expandable metallic stent

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