Efficacy and safety of therapeutic ERCP in patients with cirrhosis: a large multicenter study CME

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Background and Aims: Patients with cirrhosis may be less than optimal candidates for ERCP because of underlying ascites, coagulopathy, encephalopathy, and other problems. Although the risks of surgery in patients with cirrhosis are well known, few data are available regarding ERCP in patients with cirrhosis. We performed a retrospective, multicenter study of ERCP in patients with cirrhosis to evaluate outcomes, efficacy, and safety.

Methods: Multicenter retrospective study.

Results: A total of 538 ERCP procedures were performed on 328 patients with cirrhosis. A total of 229 patients had Child-Pugh (CP) class A, 229 patients had CP class B, and 80 patients had CP class C. Thrombocytopenia and coagulopathy were corrected before ERCP. The 30-day, procedure-related adverse events included post-ERCP pancreatitis (n = 25, 4.6%: 21 mild, 3 moderate, 1 severe), hemorrhage (n = 6, 1.1%), cholangitis (n = 15, 2.8%), perforation (n = 2, 0.4%), aspiration pneumonia (n = 5, 0.9%), bile leakage (n = 1, 0.2%), cholecystitis (n = 1, 0.2%), and death (n = 1, 0.2%). There was a higher incidence of adverse events in patients with CP class B and C disease when compared with those with CP class A disease (11.4%, 11.3%, and 6.1%, respectively; $P = .048$). There was no correlation between the risk of significant hemorrhage and the presence of coagulopathy or CP class, even in those who underwent a sphincterotomy. The presence of poorly controlled encephalopathy correlated with a higher overall adverse event rate ($P = .003$). Sub-analysis revealed that patients without primary sclerosing cholangitis had a significantly higher overall rate of adverse events, pancreatitis, bleeding, and cardiopulmonary adverse events after ERCP when compared with those with primary sclerosing cholangitis.

Conclusions: Our study was performed on a large series of patients with cirrhosis undergoing ERCP. Overall, the adverse events seen in patients with cirrhosis are similar to those seen in the general population of patients undergoing ERCP, although patients with CP classes B and C have higher adverse event rates compared with those with CP class A. Patients with cirrhosis without primary sclerosing cholangitis had significantly greater adverse event rates when compared with patients with primary sclerosing cholangitis. (Gastrointest Endosc 2016;83:353-9.)

ERCP remains one of the most widely performed and highest-risk endoscopic procedures.[1] Patients with liver cirrhosis who undergo endoscopy have additional risks and higher rates of adverse events as a result of liver dysfunction, portal hypertension, coagulopathy, and other difficulties.[2,3] It has long been established that patients with underlying liver disease, especially cirrhosis, are at increased risk of poor outcomes and adverse events when undergoing surgical procedures and anesthesia when compared with patients who do not have underlying liver disease.[4-6] Although surgery may be completely contraindicated in some patients, such as those with severe

Abbreviations: CP, Child-Pugh; INR, international normalized ratio; PSC, primary sclerosing cholangitis.

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chronic hepatitis, many patients with cirrhosis from a variety of causes (including severe chronic hepatitis) will develop medical problems best served by an ERCP.[7] Little is known about the risk of ERCP in patients with cirrhosis, and there is a paucity of literature available regarding this topic. The objective of this current, large, multicenter, retrospective study was to determine the efficacy and safety of therapeutic ERCP in patients with liver cirrhosis.

METHODS

We performed a multicenter retrospective search for all patients with cirrhosis who underwent a therapeutic ERCP from June 2003 to August 2014 at the University of Utah Health Science Center in Salt Lake City, Utah and Jefferson University School of Medicine in Philadelphia, Pennsylvania. Enrolled patients had a diagnosis of cirrhosis based on medical records, laboratory testing, liver biopsies, and the results of imaging studies. Patients were excluded if they did not have an established diagnosis of cirrhosis, were aged <18 years, or were pregnant. Data were collected on patient demographic characteristics, etiology of cirrhosis, before-procedure laboratory values, and Child-Pugh (CP) scores at the time of procedure, ERCP indications, procedural details, procedure-related adverse events, and patient mortality.

All patients underwent routine testing for prothrombin time, international normalized ratio (INR), and a platelet count a week before undergoing the ERCP if they were outpatients or the night before endoscopy if they were inpatients. Patients were given vitamin K and/or fresh frozen plasma to ensure that the INR was <1.5. Similarly, thrombocytopenic patients were infused with platelets before the ERCP to ensure that the platelet count was >50,000/mm^3.

Follow-up information was obtained through review of medical records and follow-up according to protocol: all patients received a follow-up telephone call 24 hours after the procedure to assess for immediate adverse events. Follow-up information was obtained in several ways. First, all patients were instructed to call the endoscopist who performed their procedure in the event of an adverse event. Second, patients were instructed to return to the performing institution for an adverse event that was felt to warrant evaluation and/or treatment. If they were seen at another institution, patients were instructed to have the treating physicians call the hospital where the ERCP was performed. Patients were contacted by telephone by the endoscopist to review brush cytology and/or fluorescence in situ hybridization results as these became available. Finally, all patients in this study were being followed concomitantly by personnel in our respective hepatology clinics, who also would have been able to identify adverse events.

Single variables were evaluated by using logistic regression to predict associations between the test variable and adverse events. P values $\leq .05$ were considered significant. The study was institutional review board approved.

RESULTS

A total of 538 ERCP procedures were performed on 328 patients with cirrhosis (64% men, mean ± standard deviation [SD] age 53.2 ± 14.4 years) and were included in the analysis. The etiologies of cirrhosis per procedure were as follows: alcohol abuse (n = 23, 4.1%), viral hepatitis (n = 73, 13.6%), primary sclerosing cholangitis (PSC) (n = 376, 70.2%), non-alcoholic fatty liver disease (n = 6, 1.1%), and cryptogenic cirrhosis (n = 59, 11%).

Seventy percent of ERCP procedures involved the prophylactic use of antibiotics. Antibiotics were used in patients with known PSC or confirmed biliary obstruction. We segregated patients based on CP classification. A total of 229 patients had CP class A, 229 had CP class B, and 80 had CP class C. Patients were sedated based on institutional protocols and physician preferences. A total of 266 patients underwent ERCP with general anesthesia, and 272 patients underwent ERCP with monitored anesthesia care. All patients underwent ERCP in the prone position. No patients required conversion to endotracheal intubation from monitored anesthesia care. Anesthesia was administered by anesthesiologists or certified nurse anesthetists in all cases. Coagulopathy was corrected to the extent possible before ERCP.

Indications for ERCP were as follows: choledocholithiasis (n = 35, 6.5%), biliary strictures in need of endoscopic sampling and therapy (n = 379, 70.4%), recurrent acute pancreatitis (n = 22, 4.1%), ascending cholangitis (n = 36, 6.7%), and other (pancreatic duct stones, abnormal GI imaging, abnormal liver function test results thought to be from biliary disease, etc) (n = 66, 12.3%). The baseline INR of the patients evaluated was as follows: <1.7 (n = 492), 1.7-2.2 (n = 33), and >2.2 (n = 13). The mean platelet count was 105,000/mm^3 (range 29,000-193,000/mm^3).

Patients underwent a wide range of therapeutic maneuvers during ERCP, which were individualized based on indications and intraprocedural findings. A total of 274 patients (51%) underwent placement of one or more biliary stents, 87 patients (16.2%) underwent a biliary sphincterotomy, and 8 patients (1.5%) underwent a pancreatic sphincterotomy. A total of 42 patients (7.8%) underwent balloon dilation of biliary strictures to facilitate drainage, stent placement, stone removal, or a combination thereof. Trainees participated with experienced interventional endoscopists in almost all of these cases. Patient demographic characteristics and procedure characteristics are summarized in Table 1.