

# Clinical Yield of Diagnostic Endoscopic Retrograde Cholangiopancreatography in Orthotopic Liver Transplant Recipients With Suspected Biliary Complications

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Diagnostic endoscopic retrograde cholangiopancreatography (D-ERCP) is commonly performed for the evaluation of biliary complications after orthotopic liver transplantation (OLT). This practice is contrary to the national trend of reserving endoscopic retrograde cholangiopancreatography (ERCP) for therapeutic purposes. Our aim was to evaluate the clinical yield and complications of D-ERCP in OLT recipients. In this retrospective study, 165 OLT recipients who underwent ERCP between January 2006 and December 2010 at the University of Michigan were divided into 2 groups: (1) a therapeutic endoscopic retrograde cholangiopancreatography (T-ERCP) group (if they met prespecified criteria that suggested a high likelihood of endoscopic intervention) and (2) a D-ERCP group (if there was clinical suspicion of biliary disease but they did not meet any criteria). The 2 groups were compared with respect to the proportion of subjects undergoing high-yield ERCP, which was defined as a procedure resulting in a clinically important intervention that modified the disease course. 66.3% of the D-ERCP procedures were classified as high-yield, whereas 90.1% of the T-ERCP procedures were ( $P < 0.001$ ). Serious complications were infrequent in both groups. A survey of practitioners caring for OLT recipients suggested that the rate of high-yield D-ERCP seen in this study is congruent with what is considered acceptable in clinical practice. In conclusion, although T-ERCP is more likely to reveal a pathological process requiring an intervention, D-ERCP appears to be an acceptable clinical strategy for OLT recipients because of the high likelihood of a high-yield study and the low rate of serious complications. *Liver Transpl* 18:1479-1484, 2012. © 2012 AASLD.

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Endoscopic retrograde cholangiopancreatography (ERCP), initially developed as a diagnostic test, has evolved into a mature therapeutic platform for various

pancreaticobiliary interventions.<sup>1</sup> The concurrent maturation of endoscopic ultrasound and magnetic resonance cholangiopancreatography (MRCP) now

Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; AST, American Society of Transplantation; CT, computed axial tomography; D-ERCP, diagnostic endoscopic retrograde cholangiopancreatography; ERCP, endoscopic retrograde cholangiopancreatography; HYC, high-yield cholangiography; MRCP, magnetic resonance cholangiopancreatography; OLT, orthotopic liver transplantation; PEP, post-endoscopic retrograde cholangiopancreatography pancreatitis; T-ERCP, therapeutic endoscopic retrograde cholangiopancreatography.

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allows highly accurate pancreaticobiliary imaging without the significant risks of ERCP.<sup>2-4</sup>

Consequently, the utilization of diagnostic endoscopic retrograde cholangiopancreatography (D-ERCP) has steadily declined in favor of less invasive but diagnostically comparable endoscopic ultrasound and MRCP, reserving ERCP for patients with a high pretest probability of therapeutic intervention.<sup>1,5</sup> This trend is consistent with recent clinical practice guidelines on the role of endoscopy in the evaluation of choledocholithiasis and with the National Institutes of Health consensus statement on ERCP for diagnosis and therapy: both favor less invasive tests over ERCP in the diagnosis of biliary disease.<sup>6,7</sup>

Despite the widespread practice of reserving ERCP for patients with a high likelihood of therapeutic intervention, the evaluation of biliary complications in recipients of orthotopic liver transplantation (OLT) remains an area in which D-ERCP is commonly performed.<sup>8,9</sup> This incongruence with contemporary ERCP practice may be due to multiple factors, including the high prevalence of biliary disease in OLT recipients,<sup>10</sup> the absence of data supporting the widespread use of MRCP in this patient population,<sup>11</sup> and the low reported rate of post-endoscopic retrograde cholangiopancreatography pancreatitis (PEP) in transplant patients.<sup>12</sup>

Indeed, the evaluation of biliary complications after liver transplantation may be one of the few scenarios in which D-ERCP remains appropriate, although data to support this approach are lacking. We hypothesized that OLT recipients may undergo D-ERCP excessively, and this places them at unnecessary risk that could be avoided by the more routine use of noninvasive evaluations. As such, we sought to determine the clinical yield and complications of D-ERCP in OLT recipients in an effort to better define the risk-benefit ratio of this strategy.

## PATIENTS AND METHODS

To test our hypothesis, we performed a single-center, retrospective cohort analysis comparing the clinical outcomes and complications for OLT recipients undergoing ERCP for diagnostic purposes (D-ERCP) and OLT recipients undergoing ERCP for therapeutic purposes [therapeutic endoscopic retrograde cholangiopancreatography (T-ERCP)]. A survey of the perceptions of liver transplant professionals on this topic was also performed.

### Patients

After approval of the research protocol by the institutional review board of the University of Michigan, all adult patients undergoing OLT at the University of Michigan from January 1, 2006 to December 31, 2010 were identified from an internal administrative database. The transplant patients' electronic medical records were manually reviewed to determine whether

or not each patient had undergone ERCP after transplantation. OLT recipients who had undergone ERCP at least once served as the study population.

### Data Extraction

After eligible subjects were identified, the electronic medical record of each patient was reviewed, and clinical, laboratory, and radiographic data were abstracted to standardized forms in a duplicate and independent fashion by 2 investigators (B.J.E. and A.T.D.). Discrepancies were discussed by the investigators and resolved by consensus. The following data were extracted when they were available: age; indication for OLT; time between OLT and index ERCP; pre-ERCP liver function test results (aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, and total bilirubin), pre-ERCP liver biopsy results; pre-ERCP imaging; pre-ERCP peritoneal fluid bilirubin levels; indication for ERCP (based on progress notes or procedure reports); ERCP findings; liver function test results 2 to 3 weeks after ERCP; and complications developing within 3 weeks of ERCP, including pancreatitis, bleeding, perforation, infection, and morbidity related to anesthesia (all were defined with consensus criteria).<sup>13,14</sup> Only data pertaining to a subject's first posttransplant ERCP procedure were extracted.

### Study Groups

Eligible patients were divided into 2 groups: the D-ERCP group and the T-ERCP group. The T-ERCP consisted of patients undergoing ERCP for one of the following indications: (1) evidence of a bile duct stone, cast, or stricture on percutaneous transhepatic cholangiography, MRCP, computed axial tomography (CT), or transabdominal ultrasound; (2) abnormal liver tests and biliary ductal dilation on percutaneous transhepatic cholangiography, magnetic resonance imaging, CT, or transabdominal ultrasound; (3) evidence of a bile leak on a radionuclide scan and/or peritoneal fluid aspirate showing a fluid-to-serum bilirubin ratio  $\geq 2$ ; or (4) a liver biopsy sample indicating a large bile duct obstruction (as evidenced by some combination of centrilobular canaliculi cholestasis, an intense periportal cholestatic ductular reaction, neutrophil invasion of ducts, biliary plugging, and dilation/proliferation of biliary ductules). In clinical practice, any of these scenarios would justify ERCP immediately with the intent to provide therapy. All other patients not meeting these criteria but clinically suspected to have biliary disease were assigned to the D-ERCP group.

### Study Outcomes

The primary endpoint of the study was whether or not a study patient underwent high-yield cholangiography (HYC), which was characterized as a procedure providing the opportunity for a clinically important

intervention that modified the disease course. Specifically, HYC was defined as any of the following: (1) ERCP in which a stone, cast, or bile leak was definitively identified; (2) ERCP in which stent placement across a stricture resulted in a >50% reduction of the 2 most elevated liver function tests within 2 weeks of the intervention; and (3) ERCP in which a biliary sphincterotomy for ampullary stenosis resulted in a >50% reduction of the 2 most elevated liver function tests within 2 weeks of the intervention. There were several scenarios suggestive of HYC but not specifically meeting the aforementioned criteria. In those cases, the ERCP findings and clinical outcomes were presented to a panel of 3 arbiters (an ERCP endoscopist, a transplant surgeon, and a transplant hepatologist) who were blinded to the patient group, and whether or not the ERCP procedure was high-yield was adjudicated by majority decision.

The secondary endpoints of the study were the frequency and type of post-ERCP complications. As mentioned previously, the complications of interest were pancreatitis, bleeding, perforation, infection, and morbidity related to anesthesia; all were defined with standard criteria.<sup>13,14</sup>

### Statistical Analysis and Implications of the Results

We assumed that 95% of the T-ERCP subjects would undergo HYC; this accounted for the small percentage of false-positive noninvasive imaging tests that would lead to occasional low-yield procedures in this group. We estimated that with at least 118 subjects (59 per study arm), the study would have 80% power to detect a 20% difference in HYC between the T-ERCP group (95% HYC) and the D-ERCP group (75% HYC) on the basis of Fisher's exact test with a 2-sided significance level of 0.05. A difference of less than 20% between the groups would lead to the conclusion that the diagnostic yields of D-ERCP and T-ERCP are essentially equivalent in OLT recipients, and this would cause us to reject our hypothesis and accept that a strategy of initial D-ERCP is justifiable for this patient population.

For the analysis of the primary endpoint, the difference in the proportions of patients undergoing HYC in the D-ERCP group and the T-ERCP group was analyzed with Fisher's exact test, with a final 2-sided *P* value < 0.05 indicating statistical significance. The secondary endpoint was also analyzed with Fisher's exact test, although the sample size was not large enough to determine equivalence in complication rates between the 2 groups.

### Practitioner Survey

Because there were no prior studies exploring the role of D-ERCP in transplant practice and the acceptable rate of negative ERCP in a patient population is a subjective value judgment, we conducted a survey

exploring provider perceptions of the appropriateness of D-ERCP in OLT recipients. An electronic survey was designed to assess the current practices and perceptions of transplant surgeons, transplant hepatologists, and endoscopists who perform ERCP in transplant recipients with respect to the utilization of various diagnostic tests, including D-ERCP, in OLT recipients. Two questions within the survey directly addressed the main focus of this study:

1. In transplant recipients with a duct-to-duct anastomosis, what do you believe is a reasonable rate of negative ERCP results (ie, ERCP by which no relevant pathological process is identified or treated)? In other words, out of every 10 ERCP procedures, it is acceptable to have X or fewer that are negative/normal.
2. In nontransplant recipients, what do you believe is a reasonable rate of negative ERCP results (ie, ERCP by which no pathological process is identified or treated)? In other words, out of every 10 ERCP procedures, it is acceptable to have X or fewer that are negative/normal.

A list of survey participants and corresponding e-mail addresses was generated from member directories of the American Society for Gastrointestinal Endoscopy (ASGE; ie, endoscopists) and the American Society of Transplantation (AST; ie, surgeons and hepatologists). Survey recipients were asked to participate only if they were involved in the care of liver transplant recipients as a transplant surgeon, a transplant hepatologist, or an endoscopist performing ERCP in transplant recipients. Consent to participate in this study was inferred from the completion of this voluntary and anonymous survey, which was approved by the institutional review board of the University of Michigan.

Surveys were distributed electronically in September 2011, with a reminder e-mail sent 2 weeks later. All responses received before October 13, 2011 were included in the analysis. The statistical difference between the responses to the 2 questions was analyzed with the Student *t* test.

## RESULTS

### Patients

During the 5-year study period, 406 liver transplants were performed in adults at the University of Michigan Medical Center. One hundred sixty-seven of these transplants in 165 patients were complicated by actual or suspected biliary complications prompting ERCP (2 subjects underwent 2 transplants during the study period, and each subject required ERCP at least once).

Patients ranged in age from 28 to 70 years (mean = 52.5 years). Sixty-five (39%) were women, and 100 (61%) were men. The most common etiologies of end-stage liver disease were hepatitis C virus (44%),

TABLE 1. Characteristics of the Study Population

	D-ERCP (n = 86)	T-ERCP (n = 81)	P Value
Mean age (years)	51.9	53.3	
Females [n (%)]	33 (38.4)	32 (39.5)	
Males [n (%)]	53 (61.6)	49 (60.5)	
Mean time between OLT and ERCP (months)	2.97	2.93	
Etiology [n (%)]			
Hepatitis C virus	37 (43)	37 (46)	
Alcohol	22 (26)	13 (16)	0.09
Cryptogenic cirrhosis	7 (8)	6 (7)	
Nonalcoholic steatohepatitis	5 (6)	6 (7)	
Mean alanine aminotransferase before ERCP (IU/L)	218	141	0.01
Mean alkaline phosphatase before ERCP (IU/L)	295	239	0.07
Mean total bilirubin before ERCP (MG/DL)	4.96	2.70	<0.01
Suspected biliary obstruction before ERCP [n (%)]	61 (71)	29 (36)	<0.01
Documented biliary obstruction during ERCP [n (%)]	40 (47)	38 (47)	0.96
Suspected bile leak before ERCP [n (%)]	38 (44)	48 (59)	0.05
Documented bile leak during ERCP [n (%)]	24 (28)	45 (56)	<0.01

NOTE: Several patients in both groups were suspected of having concurrent biliary obstructions and bile leaks. Seventeen percent of high-yield ERCP procedures confirmed concurrent biliary obstructions and bile leaks.

alcohol (19%), cryptogenic cirrhosis (7.2%), and non-alcoholic steatohepatitis (6.6%; Table 1).

### D-ERCP Versus T-ERCP

According to our predefined criteria, 86 ERCP procedures (51.5%) were performed for diagnostic purposes, and the remaining 81 were performed for therapeutic reasons. The characteristics of the patients in the D-ERCP and T-ERCP groups, including the results of pre-ERCP liver function tests, the numbers of patients with suspected biliary obstructions or bile leaks, and the number of patients with confirmed biliary pathologies, are also listed in Table 1.

### ERCP Indications

Eighty-four of the 86 D-ERCP patients were suspected of having biliary disease on the basis of abnormal liver function tests, but there was no associated radiographic evidence of biliary pathology. Sixty-three of these D-ERCP patients had undergone at least 1 negative radiographic test (ultrasound, CT, hepatobiliary iminodiacetic acid scan, or magnetic resonance imaging). The remaining 23 had abnormal liver tests but underwent no structural evaluation before ERCP. Two patients in the D-ERCP group did not have abnormal liver function tests; both of these patients underwent cholangiography for an evaluation of unexplained fever and leukocytosis in the context of a small amount of intra-abdominal fluid visualized by transabdominal ultrasound. All but 2 patients in the T-ERCP group met at least 1 of the eligibility criteria listed in the Patients and Methods section; 2 patients underwent ERCP for the retrieval of proximally migrated bile duct stents placed during transplantation.

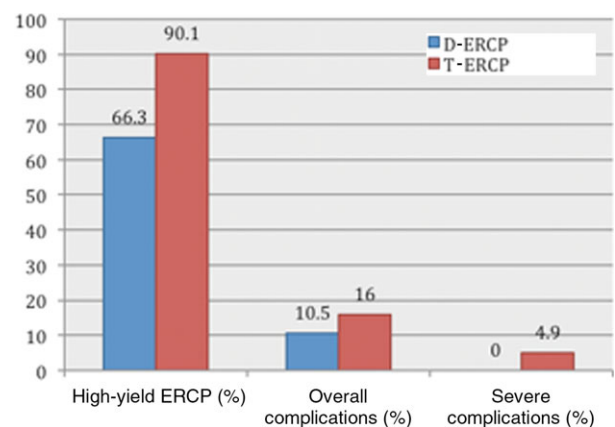


Figure 1. Percentages of high-yield ERCP procedures and overall and severe complications in the D-ERCP and T-ERCP groups.

### ERCP Yield

Overall, 130 of the 167 ERCP procedures (78%) performed in the study population were classified as high-yield by the investigators, and the remaining 37 procedures (22%) were not. In the D-ERCP group, 66.3% of the procedures (57/86) were considered HYC, whereas 90.1% (73/81) were in the T-ERCP group. This difference was statistically significant ( $P < 0.001$ ; Fig. 1).

### Complications

Twenty-two ERCP procedures (13.2%) resulted in complications of varying severity. Nine of these occurred in the D-ERCP group, and 13 occurred in the T-ERCP group ( $P = 0.36$ ; Fig. 1).

Four complications were severe in nature. One patient experienced an iatrogenic bile duct perforation

that required surgical intervention and a prolonged stay in the intensive care unit, and it eventually led to death. Another patient experienced a retroperitoneal perforation during cannulation and rapid occlusion of an indwelling endobiliary stent; this combination resulted in bacteremia and hypotension. A third patient developed an occlusion of his endobiliary stent that was complicated by ascending cholangitis and sepsis syndrome. The last patient developed massive, hemodynamically significant postsphincterotomy hemorrhaging that required angiographic intervention and a 10-day intensive care unit stay. All 4 of these severe complications occurred in the T-ERCP group.

Three patients (1.8%) developed PEP: 2 cases were mild, and 1 was moderate. None of these cases of pancreatitis resulted in any long-term adverse sequelae. Two of these complications occurred after T-ERCP, and 1 occurred after D-ERCP.

The remaining 15 complications were all related to endobiliary stent dysfunction (obstruction or migration) resulting in abdominal pain and/or abnormal liver function tests. All these complications were managed by repeat ERCP, and in several cases, a brief hospitalization was required.

### Practitioner Survey Results

In all, 5768 surveys were distributed electronically (1537 to AST members and 4231 to ASGE members). The majority of the surveys distributed to ASGE members were expected to reach physicians not involved in the care of liver transplant recipients. Similarly, some of the surveys distributed to AST members were expected to reach physicians caring for recipients of nonliver solid organs.

If we assume that there are 120 liver transplant centers in the United States and we estimate that each transplant center has approximately 10 physicians who care for liver transplant patients (3 surgeons, 3 hepatologists, and 4 endoscopists), approximately 1200 eligible physicians could have received the survey. One hundred thirty-seven (11%) were completed and analyzed. Seventy-four of the respondents were 75 endoscopists, 37 were hematologists, and 25 were transplant surgeons.

The mean number of negative ERCP procedures per 10 procedures in liver transplant recipients considered acceptable by our survey respondents was 3.3 (95% CI = 3.04-3.62). In contrast, the mean number of negative ERCP procedures per 10 procedures in nonliver transplant patients considered acceptable was 2.5 (95% CI = 2.2-2.83). This difference was statistically significant ( $P < 0.01$ ). In other words, physicians judged it appropriate for ERCP in OLT recipients to result in a clinically important intervention at a rate of 67%.

### DISCUSSION

In this study, ERCP performed with the primary intent of delivering therapy (T-ERCP) was significantly

more likely than D-ERCP to reveal a pathological process requiring endoscopic intervention. Nevertheless, 2 of every 3 D-ERCP procedures were high-yield examinations and revealed a clinically relevant pathological finding; this led us to question our hypothesis that D-ERCP is overused in OLT recipients. The overall rate of serious ERCP-related complications was low in both groups, as was the risk of PEP.

Although there was a statistically significant difference between the 2 groups, the high rate of high-yield D-ERCP and the low risk of complications in this patient population suggest that D-ERCP in liver transplant recipients may in fact be a justifiable clinical strategy. Moreover, the delay in care necessary to conduct a full pre-ERCP diagnostic evaluation, the cost savings associated with not mandating MRCP to prove the necessity of ERCP in all intermediate-risk cases, and the importance of excluding biliary complications in real time are additional justifications for D-ERCP in OLT recipients.

Indeed, the 66% rate of high-yield D-ERCP in this study is congruent with the acceptable rate of negative ERCP reported by our survey respondents, who in aggregate indicated that a mean of 3.3 or fewer negative/normal ERCP procedures per every 10 procedures in OLT recipients is justifiable.

Ultimately, the acceptable rate of negative ERCP in transplant recipients is a value judgment made by individual practitioners and based on the perceived pretest probability of biliary complications, the perceived absence of an adequate and timely alternative diagnostic method, and the expected complication rate of the procedure. Although this study cannot produce definitive recommendations, it is the first to provide objective data about the diagnostic yield and complications of D-ERCP that can inform the decision-making process influencing this value judgment.

Four patients in our study developed serious complications related to ERCP. Although all 4 of these patients were in the T-ERCP group, there is no reason to believe that complications of this magnitude cannot occur in patients undergoing D-ERCP. Therefore, even though the results of this analysis may support a strategy of D-ERCP in select OLT recipients, the risk-benefit ratio of subjecting individual patients to ERCP should be thoughtfully considered in every case. The decision to proceed with ERCP in transplant recipients should never be taken lightly because of the small but real risk of a life-threatening complication. Moreover, additional studies are necessary to assess the utility of MRCP in low-urgency, moderate-probability cases of suspected biliary obstruction.

Another finding of this study that warrants further discussion is the very low rate of PEP in liver transplant recipients. Notably, we included only patients' first posttransplant ERCP procedures in this study, and the large majority of these subjects had not undergone ERCP before transplantation. The first ERCP procedure is believed to confer the highest risk of pancreatitis because most subsequent procedures will be performed through an existing biliary

sphincterotomy, which protects against PEP by separating the biliary and pancreatic orifices. Therefore, the 1.8% rate of PEP would likely have been much lower if all post-OLT ERCP procedures had been considered in this analysis. The overall rate of complications and the low risk of pancreatitis are consistent with previously reported data for transplant patients,<sup>12,15,16</sup> and they underscore the importance of further studies aimed at determining the factors that protect transplant recipients from PEP. Deciphering these factors may have implications for understanding the pathophysiology of PEP and preventing pancreatitis in nontransplant patients undergoing ERCP.

The results of this study should be interpreted in the context of several important limitations. First, this was an observational study in which confounding variables may have led to important differences between the groups that could have affected the high-yield ERCP rate. For example, it is reasonable to assume that some of the D-ERCP patients could have actually been included in the T-ERCP group had additional testing been performed (not all D-ERCP patients had undergone transabdominal ultrasound, radionuclide scans, and MRCP). These possible misclassifications may have inflated the HYC rate in the diagnostic group. Second, our study used a relatively small sample from a single medical center, and thus the results may not be universally generalizable. Third, the retrospective nature of the study makes it likely that not all complications were captured, and our reported PEP rate may be falsely low. Finally, the survey response rate was only 11%, and our response sample may not have accurately reflected the perceptions of the liver transplant community at large. Nevertheless, this study is the first to comprehensively evaluate the common practice of D-ERCP in liver transplant recipients.

In summary, D-ERCP appears to be a reasonable clinical approach in liver transplant recipients with suspected biliary complications because of the high likelihood of a high-yield study and the low rate of complications. To optimize the risk-benefit ratio of ERCP in this patient population, further studies are needed for identifying combinations of easily accessible clinical and laboratory factors that predict the presence of biliary pathologies. Moreover, additional investigations focusing on understanding the low risk of PEP in OLT recipients are warranted.

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