

Early Complications of Therapeutic Endoscopic Retrograde Cholangiopancreatography: A Prospective Tertiary Hospital Study

Islam MS¹, Alam AHMT², Ahmed SU³, Zaman KS⁴, Islam MN⁵

Abstract

There is a lack of tertiary hospital prospective studies on complications of diagnostic and therapeutic endoscopic retrograde Cholangiopancreatography (ERCP). We studied 233 consecutive patients undergoing ERCP at Department of general surgery, Bangabandhu Sheikh Mujib Medical University (BSMMU) over a 1-year period Since March, 2005 to February, 2006. General and ERCP-specific major complications were predefined. Data were collected at the time of ERCP, before discharge, and in cases of readmission within 30 days. ERCP was defined as therapeutic when endoscopic sphincterotomy, precut or drainage had been carried out, singularly or in combination. Among 233 patients, successful diagnostic and therapeutic ERCP was performed in 97.42% with an overall complication rate of (9.01%). Liver abscess were (1.69%) in number respectively. One patient needed ICU admission in pancreatitis. One patient needed surgical intervention in liver abscess patients The incidence of pancreatitis was 5.15% and hemorrhage (1.69%). Major complications are mostly associated with therapeutic procedures. A more selected and safer use may be expected to further limit the adverse events of ERCP.

Introduction

Department of general surgery at BSMMU hospital provides a diagnostic and therapeutic ERCP service for patients. ERCP was first introduced in 1968¹ and since then this procedure is performed for diagnostic and therapeutic purposes with risks of complications. However, to date there are no published data on the spectrum and rate of early ERCP complications in Bangladesh. The aim of this prospective study was to evaluate all consecutive ERCPs performed over a one year period and to determine the spectrum and rate of early complications of therapeutic ERCP.

Materials and Methods

An ERCP data sheet was designed for all patients undergoing ERCP at Department of general surgery, BSMMU Since March, 2005 to February, 2006. This data sheet held information on patient demographics, indication for ERCP, relevant investigation before ERCP and other details of the therapeutic procedure. The data sheet was to be filled by us at the time of giving the ERCP report, which usually was just after the procedure. In addition to the above information, we recorded information regarding the names and dosages of drugs used during the procedure and the therapeutic procedures undertaken, including sphincterotomy, stone extraction, stenting and stricture dilatation. Overall success of the procedure was graded as complete or failed. Final diagnosis and any immediate complications were also noted on the data sheet. Patients were informed via a notice in their ERCP information sheet, usually sent to patients with notification of their appointment date and time that there was a possibility they may be contacted within a few weeks of the ERCP by telephone regarding any major complications they may have suffered after their procedure. ERCP was defined as a therapeutic procedure where endoscopic sphincterotomy or drainage procedure was carried out alone or in combination. Severity of complication was graded as mild if the complication resulted in the patient staying in hospital for 1 to <4 days, moderate for 4 to 10 days, and severe for >10 days or if the patient required intensive care unit (ICU) admission or surgical or invasive radiological intervention. Pancreatitis was defined as significant post-ERCP abdominal pain requiring i.v analgesia and amylase greater than one and a half times the normal. Significant bleeding was defined as clinical evidence of hemorrhage requiring blood transfusion only and not minor endoscopic bleeding. All patients, not already on antibiotics, with cholestatic liver function tests and suspected biliary obstruction received prophylactic antibiotics. The standard antibiotic protocol was a combination of cephadrine and gentamicin given intravenously. Patients already on antibiotics continued treatment and additional antibiotics were administered to ensure adequate coverage of gram negative organisms. ERCP related complications were noted by contacting patients who lived outside the BSMMU hospital area via telephone 30 days after the procedure. If a patient was admitted with an ERCP related complication, the endoscopist or the general surgery department was routinely informed. However, the medical records of all patients who had undergone ERCP were reviewed within 30 days after the procedure to ensure reporting of complications was not missed.

All data were entered on an Excel spreadsheet and relevant analysis derived.

1. Corresponding Author: Dr. Md. Saiful Islam
Resident (Medical Officer)
Bangabandhu Sheikh Mujib Medical University, Dhaka
2. Professor Dr. AHM Towhidul Alam
Professor, Department of surgery
Bangabandhu Sheikh Mujib Medical University, Dhaka
3. Dr. Saif Uddin Ahmed
Associate professor, Department of surgery
Bangabandhu Sheikh Mujib Medical University, Dhaka
4. Dr. Kazi Shamim Uzzaman
Assistant professor, Department of orthopedic surgery
Shaheed Suhrawardy Medical College, Dhaka
5. Dr. Farhana Afroz
Assistant professor, Department of pathology
Green life Medical College, Dhaka
6. Dr. Farzana Yesmin
OSD, DG Health, Mohakhali, Dhaka
7. Dr. Md. Nazrul Islam
Resident Surgeon, Department of orthopedic surgery
Shaheed Suhrawardy Medical College, Dhaka

Results

A total of 233 patients were audited and complete data were available. Sex distribution for ERCP was female 133 and male 100. In therapeutic ERCP female was 60.50% and male was 39.50%. The youngest patient undergoing the ERCP was 8 years while the eldest was 90 years. Average age of the patients was 43.57 years. 63.52% of the ERCP were performed as outpatient or day stay procedures and 36.48% of were inpatient patients.

Fig-I: Sex group of therapeutic ERCP patients

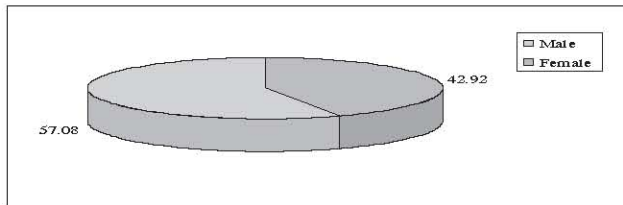


Fig-I: Shows sex group of the patients. 57.08% patients were female and 42.92% patients were male.

Table-I: Indications for ERCP.

Indication	n	%
Malignant biliary obstruction	65	27.90
Chole docholithiasis	58	24.89
Pancreatitis	27	11.59
Biliary ascariasis	17	7.29
Cholestatic liver function test	14	6.00
Post operative biliary leakage	11	4.72
Post operative biliary stricture	9	3.86
Sphincter of oddi dysfunction	9	3.86
Hepatolithiasis	5	2.15
Blocked stent	4	1.72
Chole dochoenteric fistula	4	1.72
Chole dochal cyst	2	.86
Primary sclerosing cholangitis	2	.86
Caroli's disease	1	.43
Others	5	2.15
Total	233	100

Indications in patients presenting for ERCP are listed in Table-I. Malignant biliary obstruction 27.90% was the most common followed by Chole docholithiasis 24.89%. Pancreatitis 11.59% was the 3rd position. 7.29% patients were presented with biliary ascariasis. 6.00% patients were presented with cholestatic liver function test. 4.72% patients were presented with post operative biliary leakage. 3.86% patients were presented with post operative biliary stricture,

3.86% patients were presented with sphincter of oddi dysfunction, 2.15% patients were presented with hepatolithiasis.1.72% patients were presented with blocked stent. 1.72% patients were presented with chole dochoenteric fistula. .86% patients were presented with chole dochal cyst. .86% patients were presented with primary sclerosing cholangitis. .43% patient was presented with Caroli's disease. 5 (2.15%) patients were presented with other indications (1 patient with pneumobillia, 1 patient with gall bladder stone with jaundice, 1 patient with dilated biliary tree, 1 patient with gall bladder stone with cystic duct stone & 1 patient with benign distal CBD stricture).

Table-II: Features of ERCP

	Total number(N)	Percentage%
Attempt ERCP	233	100
Therapeutic	168	72.10
Diagnostic only	59	25.32
Failed ERCP	6 (4 due to gastric outlet obstruction and 2 due to Billroth II gastrectomy)	2.58

As shown in Table-II, therapeutic ERCP was done in 72.10% cases. Diagnostic ERCP was done in 25.32% cases. ERCP was unsuccessful in 2.58% patients. The predominant cause of failure was inability to reach papilla due to either gastric outlet obstruction or Billroth II gastrectomy. The success rate of ERCP was 97.42%.

Table-III: Early complications after diagnostic and therapeutic ERCP

complication	N	In Therapeutic BRCP	In Diagnostic BRCP	% Therapeutic (n=168)	% Diagnostic (n=59)	% Total (n=233)	Surgery	ICU	Mortality
Pancreatitis	12	11	1	6.54	1.69	5.15	-	1	0
Cholangitis	5	5	-	2.98	-	2.14	-	-	-
Hemorrhage	2	2	-	1.19	-	.86	-	-	-
Liver Abscess	2	2	-	1.19	-	.86	1	-	-
Total	21	20	1	11.90	1.69	9.01	1	1	0

A total of 21 complications were recorded in Table-III. 20 complications were as result of therapeutic ERCP. The most common complication was pancreatitis. After therapeutic ERCP 11 (6.54%) pancreatitis was developed. Cholangitis was developed in 5 (2.98%) patients.

Hemorrhage and Liver abscess were 2 (1.19%) in number respectively. One patient needed ICU admission due to pancreatitis. One patient needed surgical intervention in liver abscess patients. Total complication rate after ERCP was 9.01% but after therapeutic ERCP the complication rate was higher and that was 11.90%.

Table-IV: Early complications of ERCP by severity

Severity	Number (N)	Number in therapeutic ERCP	Number in diagnostic ERCP	%therapeutic (n=168)	%diagnostic (n=59)	%total (n=233)
Mild (1 to <4 days)	7	6	1	4.16	1.69	3
Moderate (4 to 10 days)	9	9	0	4.76	0	3.86
Severe	5	5	0	2.98	0	2.15
Total	21	20	1	11.90	1.69	9.01

The severities of the complications are shown in table-IV: In therapeutic ERCP mild complication was 6 (4.16%), moderate complication was 9 (4.76%) and severe complication was 5 (2.98%).

Discussion

This prospective study was carried out in BSMMU, a tertiary referral hospital in Bangladesh. With a large number of patients who underwent ERCP, more than 200 procedures per year, we believe that this series could represent the close to actual incidence of early complications developed following therapeutic ERCP from other tertiary Centers. From the present series, we performed the comparison of the incidence of procedure related complications with previous published international series. Generally, incidence of post-ERCP pancreatitis varies between (2-10%)¹³. Several approaches have been taken towards avoiding this common complication. The pharmacologic prevention of post-ERCP pancreatitis has been sought for many years. However, to date, no agent has been found to be consistently effective in a single dose⁴. These agents include platelet-activating factor inhibitors, glucagons, interleukin⁵ somatostatin⁶, gabaxete⁷ but we did not use these agents. In addition, epidemiologic analysis of the patients with post-ERCP pancreatitis demonstrate patient and procedure related risk factors so that ERCP can be avoided or modified in a technique for high risk patients. These patient related contributing factors include suspected dysfunction of sphincter of oddi (SOD), young age, normal bilirubin level and history of prior post- ERCP pancreatitis⁸. Besides post-ERCP pancreatitis, hemorrhage and cholangitis are possible early complications with the incidence of 2%⁹ and 1-3%¹⁰ respectively. Liver abscess was also found to be another significant complication following the procedure increasing morbidity and mortality in these patients. Most of these patients required intravenous antibiotics to control infection.

In this study, a total 233 cases were evaluated, 168 were therapeutic ERCP, among them 20 cases presented with post therapeutic ERCP complications. The average age of the patients was 43.56 years ranging from 8 years to 90 years. The female patients were predominant. The female predominance was found similar to Denish Lal, Mark Lane & Philip Wong¹¹.

In present series, major, indication for ERCP was malignant biliary obstruction 27.90%. Followed by Choledocholithiasis 24.89%. Then pancreatitis 11.59%, biliary ascariasis 7.29% and Cholestasis in 6.00% of cases. Patients underwent

ERCP for postoperative biliary leakage was 4.72% and postoperative biliary stricture was 3.86%.

In our study, total 233 patients were attempted for ERCP, but majority patients (72.10%) underwent therapeutic ERCP. Diagnostic ERCP was done in 25.32% cases. But ERCP was failed in 2.58% cases. The predominant cause of failure was gastric outlet obstruction.

In this study post ERCP complications was 9.01%, is quite acceptable with moderate (3.86%) to severe (2.15%) and total moderate to severe complications being only 6.01%. In this study 4.16% mild, 4.76% moderate and 2.98% severe complications were occurred after therapeutic ERCP. In therapeutic ERCP all of our moderate (4.76%) to severe (2.98%) ERCP related complications were at a total rate of 7.74%. This is near to the British survey (10%) reported by Tanner¹² and is supported by the study by Laperfido¹³. Severity of complication was graded as mild if the complication resulted in the patient staying hospital for 1 to <4 days, moderate for 4 to 10 days and severe for more than 10 days or if the patient required admission in ICU or surgical or invasive radiological intervention.

Aetiology of mild, moderate & severe post ERCP complications were different but pancreatitis was predominant in all mild, moderate and severe cases.

In this study, post ERCP complications- pancreatitis was 5.15%, cholangitis was 2.14%, haemorrhage was .86% and liver abscess was .86%. Pancreatitis is one of the common procedure related complications. The incidence of pancreatitis is comparable to the other international series (2-10%)⁹. Pancreatitis was 6.54% in the therapeutic ERCP which is consistent with the commonly quoted international rates¹¹. Among severe pancreatitis one patient needed ICU admission.

In the present series, the rate of cholangitis was to be the second common complication following therapeutic ERCP with the incidence of 2.98%, comparable to other study¹⁰. It is noted that rate of cholangitis is slightly higher than other studies. Liver abscess occurred in 1.19% patients. All the cases were severe in nature. One patient needed surgical intervention.

In the present series, the rate of hemorrhage was 1.19% in therapeutic ERCP comparable to other study¹³. It could be due to technical difficulty in performing the procedure. It is important to note, none of my patients died as a direct of the result of therapeutic ERCP.

In this study, all the 233 patients were evaluated upon the basis on clinical examination, biochemical and other investigations, complications were determined. The rate of complications after ERCP was 9.01% and in therapeutic ERCP complication rate was 11.90%. The incidence of post therapeutic ERCP is higher. Endoscopist is to be more cautious in performing therapeutic ERCP to avoid complications. The incidence and type of complications of ERCP vary widely in different circumstances. Complication appears to be related primarily to the clinical indication for procedure and to the technical skill of the endoscopist rather than to the procedure, age or general medical condition of the patients. ERCP should be done where immediate radiological & surgical treatments of complication are available.

References

1. De Palma GD, Catanzano C. Use of corticosteroids in the prevention of post ERCP pancreatitis: result of a controlled prospective study. *Am Gastroenterol* 1999;94:982-85.
2. LaFerla G, Gordon S, Archibald M, Murray WR. Hyperglycemia and acute pancreatitis. *Pancreas* 1985;1:160-63.
3. Rabenstein T, Hahn EG. Post- ERCP Pancreatitis: new momentum. *Endoscopy* 2002;34:325-9.
4. Testoni PA. Preventing post-ERCP Pancreatitis where are we? *J Pancreas* 2003;4:22-32.
5. Cavllini G, Tittobello A, Frulloni L, Masci E, Mariani A, Di Francesco V, and The gabexate in digestive endoscopy-Italian group. Gabexete for the prevention of pancreatic damage related to endoscopic retrograde Cholangiopancreatography. *N Eng J Med* 1996;335:919-23.
6. Fazel A, Quadri A, Catalano MF, Meyerson SM, Greenan JE. Does a pancreatic duct stent prevent post-ERCP pancreatitis? A prospective randomized study. *Gastrointest Endosc* 2003;57:291-94.
7. Rerknimitr R, Kullavanijaya P. Endoscopic management of cholangiocarcinoma. *J Med Assoc Thai* 2001;84:452-55.
8. Freeman ML. Prevention of post- ERCP pancreatitis: pharmacologic solution or patient selection and pancreatic stent? *Gastroenterol* 2003;124:1977-80.
9. Freeman ML, Nelson DB, Sherman S, Haber GB, Herman ME, Dorsher PJ, et al. Complications of endoscopic biliary sphincterotomy. *N Eng J Med* 1996;335:909-18.
10. Andriulli A, Caruso N, Quitadamo R, Leandro G, Spirito F, De Maino G. Antisecretory vs. antiproteastic drugs in the prevention of post- ERCP pancreatitis, the evidence-based medicine derived from a meta-analysis study. *J Pancreas* 2003;4:41-48.
11. Dinesh Lal, Mark Lane and Philip Wong. Complications of Endoscopic Retrograde Cholangiopancreatography. *Journal of the New Zealand Medical Association* 2003;116:1117.
12. Tanner AR. ERCP: present practice in a single region. Suggested standards for monitoring performance. *Eur J Gastroenterol Hepatol* 1996;8:145-8.
13. Loperfido S, Angelini G. Major early complications from diagnostic and therapeutic ERCP: a prospective multi-center study. *Gastrointest Endosc* 1998;48:1-10.