



## A PROSPECTIVE STUDY OF THERAPEUTIC BILIARY ENDOSCOPY IN A TERTIARY CARE HOSPITAL

Kannan Mariappan and Ramani Rathnavel

Dept.of Medical Gastroenterology, Govt. Rajaji Hospital, Madurai

### ARTICLE INFO

**Article History:**

Received 15<sup>th</sup> November, 2018

Received in revised form 7<sup>th</sup>

December, 2018

Accepted 13<sup>th</sup> January, 2018

Published online 28<sup>th</sup> February, 2019

**Key words:**

ERCP, Biliary pathology, Pancreatitis

### ABSTRACT

The incidence of biliary tract pathologies increases as leading to an increase in the demand of therapeutic use of endoscopic retrograde cholangio- pancreatography (ERCP). This retrospective study was carried out to assess the effectiveness of therapeutic ERCP in predominantly biliary pathology. It was a prospective observational study. Patients referred for therapeutic ERCP from January 2015 to December 2018 were reviewed by a preformed data sheet which included all the relevant details of the procedure. Of 273 patients audited, successful therapeutic ERCP was performed in 91.04% cases. Our study showed that ERCP was effective in the biliary disorders.

Copyright©2019 **Kannan Mariappan and Ramani Rathnavel**. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

### INTRODUCTION

Endoscopic Retrograde Cholangio pancreatography (ERCP) is an advanced endoscopic procedure in which a specialized side viewing duodenoscope is passed into the duodenum, allowing accessories to be pushed via biliary or pancreatic ducts for diagnostic and therapeutic intervention. It is one of the most complex endoscopic procedures, requiring specialized equipment and proficient and skilled operators and assistants. Today therapeutic ERCP is the intervention of choice for many pancreaticobiliary disorders.

We performed a retrospective audit of ERCPs performed over the last 4 years period from January 2015 to December 2018 in our Hospital.

### MATERIALS AND METHOD

Prospective evaluation of indications, findings, therapeutic interventions carried out, safety profile and technical success of endoscopic retrograde cholangiography (ERCP) carried out, during a 4 years period from January 2015 to December 2018 was done.

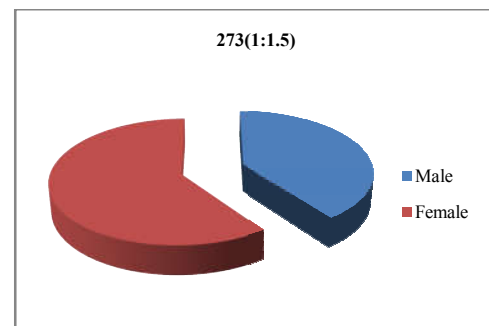
Additional information if required was obtained from patient chart review from medical records. All ERCPs were performed by two experienced operators, during the entire study period. An ethical approval was obtained from our hospital ethics committee

### RESULTS

A total of 273 ERCP procedures were carried out on 273 patients over the 4 year study period. The mean age of the patients undergoing ERCP was 51.67 years with a male female ratio of 104:152 (1:1.5)

Table 1

Number of patients	273
Mean Age	51.64 years
Male/Female ratio	01:01.5
Number of procedures	273



The pre procedure indication for ERCP was predominantly biliary indications (95.6 %) of which the vast majority was done for calculus biliary disease (Table 2) Pancreatic indications were few (4.4%).

\*Corresponding author: **Ramani Rathnavel**

Dept.of Medical Gastroenterology, Govt. Rajaji Hospital, Madurai

**Table 2** Pre procedure indications.

Indications	Number
Biliary indications	261
Common bile duct stones	189
Post-operative biliary leaks	16
Biliary strictures	23
Stent exchange/ removal	11
Biliary tumors	9
Biliary pancreatitis	13
Pancreatic indications	12
Carcinoma pancreas	12

Major reason for all biliary interventions was calculous biliary disease, requiring clearance of the common bile duct stones, post laparoscopic cholecystectomy biliary leak, biliary strictures and palliation of biliary obstruction due to malignancy.

Biliary interventions formed majority of (95.6%) all therapeutic interventions which were further comprised of papillotomy and common bile duct stone clearance with balloon or basket and biliary stenting for various indications (Table 3). Pancreatic therapeutic interventions were few. Seventeen patients had incomplete procedures due to diverse reasons which included failed cannulation. Our initial cannulation success was 89.3 %. In 29 patients we had failure in achieving deep biliary cannulation at the initial attempt. However on reattempts 24–72 hours after initial endoscopy, we succeeded in cannulation in 17 of these patients, thus giving an overall cannulation success rate of 93.7%.

**Table 3** Therapeutic Interventions

Biliary interventions	
Papillotomy and clearance of common bile duct calculi	181
Papillotomy, incomplete common bile duct clearance and biliary stenting	6
Papillotomy and biliary stenting	239
Biliary stent exchange	11
Biliary stricture dilatation	9
Precutpapillotomy	26
Pancreatic interventions	
Mass head of Pancreas	12

**Table 4** Major complications encountered are mentioned in.

Major post ERCP complications	Number of patients
Post procedure bleeding	2 (0.73%)
Perforation	nil
Post ERCP Pancreatitis	7 (2.56%)

## DISCUSSION

Our Govt. Hospital with a volume of around 60 to 70 ERCPs per year Adequate volumes are needed to maintain proficiency and skills and individual endoscopists who perform more than 40 endoscopic sphincterotomies per year<sup>2</sup> or at least one per week<sup>3</sup> have a lower complication rate than those who perform fewer procedures.

As a matter of policy we have been adhering to the recommendations of the consensus development conference sponsored by the National Institute of Health (NIH) in 2002, regarding indications for ERCP in our practice.<sup>4</sup> Since the avoidance of unnecessary ERCP is the best way to reduce complications, whenever possible we have used Magnetic Resonance Cholangiopancreatogram (MRCP) for diagnostic work, reserving ERCP as a purely therapeutic tool for the management of biliary and pancreatic disease. ERCP and

MRCP have comparable sensitivity and specificity for diagnosis of biliary and pancreatic disorders.<sup>5</sup> Most of our ERCPs were performed with a therapeutic intent. Two thirds of procedures were for therapeutic intent in a prospective survey of 2769 patients in Italy from 1992 to 1994.<sup>6</sup> With the advent and availability of new effective diagnostic tools like MRCP and EUS,<sup>7</sup> diagnostic ERCPs are hardly performed and this has been our experience as well. Despite their relative safety, diagnostic ERCPs have by no means had negligible complications. Serious complications from purely diagnostic ERCPs have been reported and this was mentioned in a study<sup>8</sup> which looked at claims for compensation from ERCP related complications. Among the nine fatal cases, the procedure was diagnostic in six, which were potentially avoidable ERCPs.

Clearance of common bile duct stones<sup>4</sup> and management of post-operative bile leaks formed the major indications for our biliary intervention.<sup>9</sup> We have undertaken ERCP as the first line therapy for the management of postoperative bile leaks as it is the accepted standard of care today. Palliation of malignant biliary obstruction formed another important indication for biliary drainage.<sup>11</sup> Placement of bridging or trans papillary pancreatic stent for pancreatic leak due to pancreatic duct disruption from trauma has been yet another indication for pancreatic endotherapy.<sup>12</sup> ERCP today is accepted as a tool for drainage of symptomatic pancreatic pseudocyst<sup>13</sup>

Though hyperamylasemia is common after ERCP occurring in up to 75% of patients, acute clinical pancreatitis, defined as a clinical syndrome of abdominal pain and hyperamylasemia requiring hospitalization is much less common. In our audit there were 7 patients (2.56%) who developed severe clinical pancreatitis. It has been our practice to avoid repeated pancreatic duct instrumentation or guide wire passage and to do limited pancreatic duct injections, which are well known risk factors for post ERCP pancreatitis.<sup>15</sup> Post ERCP acute pancreatitis can be graded as mild, moderate or severe based on the consensus definition.<sup>16</sup> Mild pancreatitis is defined as patients having serum amylase at least 3 times more than the normal 24 hours after the procedure, requiring admission or prolongation of planned admission by 2 to 3 days, moderate pancreatitis is severe enough to require hospitalization of 4 to 10 days and severe pancreatitis requires hospitalization for more than 10 days with phlegmon or pseudocyst which requires percutaneous intervention or surgery. The incidence of acute pancreatitis has been estimated in several large clinical trials and most studies demonstrate a rate of 4 to 5%. However our incidence of severe clinical pancreatitis less than 1%, may be an underestimate since being a retrospective audit only severe cases of pancreatitis requiring prolonged in hospital stay were documented. Low complication rates could also be attributed to the fact that all procedures were performed by two experienced operators during the entire study period. Operator experience and volumes are major factors determining outcomes and complications in ERCP.<sup>17</sup>

Bleeding was the most dreaded complication when therapeutic biliary interventions were first introduced.<sup>18</sup> Because of advance in equipment and better experience, it has become a relatively uncommon complication of ERCP and is mostly reported only after sphincterotomy. Post ERCP bleeding can be graded as mild, moderate or severe based on the consensus definition.<sup>16</sup> Mild bleeding is when there is clinical evidence of bleeding (not just endoscopic) with Hemoglobin(Hb) drop less

than 3 gram % and without the need for transfusion. Moderate bleeding is defined as bleeding with need for transfusion of 4 units or less, but with no angiographic intervention or surgery. Severe bleeding is deemed to have happened with transfusion requirement of 5 units or more or in situations where intervention by angiography or surgery is required to control bleeding. We had 2 cases of bleeding (0.73%). 2 patients with clinical bleed did not require blood transfusion and were managed with just local epinephrine injection and thus was deemed as mild bleeding.. Minor episodes of bleeding without >1 gram Hb drop and with good haemostasis with local therapy were not considered to be a significant complication, in our analysis. Our practice ensured a platelet count above 80,000/cc and Internationalized Ratio (INR) <1.2 as a requirement for all ERCPs which reduced complications from bleeding.<sup>19</sup>

We had an overall selective cannulation success rate of over 93.7%. We practice wire guided cannulation of the bile duct, which has improved success rates for selective biliary cannulation and reduced incidence of post ERCP pancreatitis.<sup>20,21</sup>

Limiting the privileges for therapeutic ERCP to two expert operators has probably kept the major complication rates low, despite our moderate volumes. In conclusion, our audit of ERCPs indicates judicious volumes of mostly biliary therapeutic interventions for diverse indications with technical success and low complication rates, at par with accepted international standards.

## References

1. Jowell PS, Baillie J, Branch MS, Affronti J, Browning CL, Bute BP . Quantitative assessment of procedural competence. A prospective study of training in endoscopic retrograde cholangiopancreatography. *Ann Intern Med.* 1996 Dec;125:983–989.
2. Adler DG, Baron TH, Davila RE, Egan J, Hirota WK, Leighton JA, Qureshi W, Rajan E, Zuckerman MJ, Fanelli R, Wheeler-Harbaugh J, Faigel DO, Standards of Practice Committee of American Society for Gastrointestinal Endoscopy . ASGE guideline: the role of ERCP in diseases of the biliary tract and the pancreas. *Gastrointest Endosc.* 2005 Jul; 62:1–8.
3. Rabenstein T, Schneider HT, Nicklas M, Ruppert T, Katalinic A, Hahn EG, Ell C . Impact of skill and experience of the endoscopist on the outcome of endoscopic sphincterotomy techniques. *Gastrointest Endosc.* 1999 Nov;50:628–636.
4. Cohen S, Bacon BR, Berlin JA, Fleischer D, Hecht GA, Loehrer PJ Sr, McNair AE Jr, Mulholland M, Norton NJ, Rabeneck L, Ransohoff DF, Sonnenberg A, Vannier MW . National Institutes of Health State-of-the-Science Conference Statement: ERCP for diagnosis and therapy, January 14–16, 2002. *Gastrointest Endosc.* 2002 Dec;56:803–809.
5. Soto JA, Barish MA, Yucel EK, Siegenberg D, Ferrucci JT, Chuttani R. Magnetic resonance cholangiography: comparison with endoscopic retrograde cholangiopancreatography. *Gastroenterology.* 1996 Feb; 110:589–597.
6. Loperfido S, Angelini G, Benedetti G, Chilovi F, Costan F, De BF, De Bernardin M, Ederle A, Fina P, Fratton A. Major early complications from diagnostic and therapeutic ERCP: a prospective multicenter study. *GastrointestEndosc.* 1998 Jul;48:110.
7. Palazzo L, Girollet PP, Salmeron M, Silvain C, Roseau G, Canard JM, Chaussade S, Couturier D, Paolaggi JA . Value of endoscopic ultrasonography in the diagnosis of common bile duct stones: comparison with surgical exploration and ERCP. *GastrointestEndosc.* 1995 Sep;43:225–231.
8. Trap R, Adamsen S, Hart-Hansen O, Henriksen M . Severe and fatal complications after diagnostic and therapeutic ERCP: a prospective series of claims to insurance covering public hospitals. *Endoscopy.* 1999 Feb; 31:125–130.
9. Ahmad F, Saunders RN, Lloyd GM, Lloyd DM, Robertson GS . An algorithm for the management of bile leak following laparoscopic cholecystectomy. *Ann R CollSurg Engl.* 2007 Jan; 89:51–56.
10. Sajith KG, Chacko A, Dutta AK . Recurrent acute pancreatitis: clinical profile and an approach to diagnosis. *Dig Dis Sci.* 2010 Dec; 55:3610–3616.
11. Chu D, Adler DG. Malignant biliary tract obstruction: evaluation and therapy. *J Natl Compr Canc Netw.* 2010 Sep; 8:1033–1044.
12. Kim HS, Lee DK, Kim IW, Baik SK, Kwon SO, Park JW, Cho NC, Rhoe BS. The role of endoscopic retrograde pancreatography in the treatment of traumatic pancreatic duct injury. *Gastrointest Endosc.* 2001 Jul; 54:49–55.
13. Park DH, Lee SS, Moon SH, Choi SY, Jung SW, Seo DW, Lee SK, Kim MH. Endoscopic ultrasound-guided versus conventional transmural drainage for pancreatic pseudocysts: a prospective randomized trial. *Endoscopy.* 2009 Oct; 41:842–848. Ayoub WS, Esquivel CO, Martin P. Biliary complications following liver transplantation. *Dig Dis Sci.* 2010 Jun; 55:1540–1546.
14. Badalov N, Tenner S, Baillie J. The prevention, recognition and treatment of post-ERCP pancreatitis. *JOP.* 2009; 10:88–97.
15. Cotton PB, Lehman G, Vennes J, Geenen JE, Russell RC, Meyers WC, Liguory C, Nickl N. Endoscopic sphincterotomy complications and their management: an attempt at consensus. *Gastrointest Endosc.* 1991 May; 37:383–393.
16. Testoni PA, Mariani A, Giussani A, Vailati C, Masci E, Macarri G, Ghezzi L, Familiari L, Giardullo N, Mutignani M, Lombardi G, Talamini G, Spadaccini A, Briglia R, Piazzi L, SEIFRED Group . Risk factors for post-ERCP pancreatitis in high- and low-volume centers and among expert and non-expert operators: a prospective multicenter study. *Am J Gastroenterol.* 2010 Aug; 105:1753–1761.
17. Rabenstein T, Schneider HT, Hahn EG, Ell C . 25 years of endoscopic sphincterotomy in Erlangen: assessment of the experience in 3498 patients. *Endoscopy.* 1998 Nov; 30:A194–A201.
18. Prat F, Tennenbaum R, Ponsot P, Altman C, Pelletier G, Fritsch J, Choury AD, Bernades P, Etienne JP. Endoscopic sphincterotomy in patients with liver cirrhosis. *Gastrointest Endosc.* 1996 Feb;43:Pt 1:127–131.
19. Freeman ML, Guda NM . Prevention of post-ERCP pancreatitis: a comprehensive review. *Gastrointest Endosc.* 2004 Jun; 59:845–864.
20. Lee TH, Park dH, Park JY, Kim EO, Lee YS, Park JH, Lee SH, Chung IK, Kim HS, Park SH, Kim SJ . Can wire-guided cannulation prevent post-ERCP pancreatitis? A prospective randomized trial. *Gastrointest Endosc.* 2009 Mar ;1:444–449.