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A referral Center experience



Ann Ital Chir, 2019 90, 6: 520-523
pii: S0003469X19027519
Epub Ahead of Print - Sept. 13
free reading: www.annitalchir.com

Tolga Canbak*, Aylin Acar*, Fatih Basak*, Kamil Ozdil**, Gurhan Bas***, Ethem Unal*

*Health Science University, Umraniye Training and Research Hospital, Department of General Surgery, Istanbul, Turkey

**Health Science University, Umraniye Training and Research Hospital, Department of Gastroenterology, Istanbul, Turkey

***Medeniyet University, Goztepe Training and Research Hospital, Department of General Surgery, Istanbul, Turkey

Risk factors for complications after endoscopic retrograde cholangiopancreatography. A referral Center experience

AIM: Endoscopic retrograde cholangiopancreatography (ERCP) is an important diagnostic and therapeutic tool in patients with hepato-pancreatobiliary diseases. In the present study, we sought to determine predictors of post-ERCP complications at our institution.

METHODS: A retrospective analysis of patients who underwent ERCP in between January 2010 and November 2011 was done. Demographics, indications, ERCP findings, success rate, complications and the need of repeat procedure were evaluated with special emphasis on the difficulty in cannulation procedure, the primary etiology of the disease (benign/malign) and age. Chi-square analysis was applied for statistical analysis. The differences were considered statistically significant, if the *p* value was less than 0.05.

RESULTS: A total of 112 ERCP was performed in 81 patients. Thirty-eight were male (46.9 %) and 43 were female (53.1%). Mean age was 61.3 (range 17-88), and 31 patients was seventy years and older (38.3 %). Complications were detected in 28 patients (34.6 %). Nine cases with difficult or unsuccessful cannulation (69.2 %) had complications (*p*=0.001). Patients with benign diseases showed less complications (21/70), in comparison with those with malignancies (7/11) (30 % vs. 63.6 %, respectively; *p*<0.05). Complication rate in patients 70 years and older was 32.2 % (*n*=10) compared to 35.3 % in patients younger than 70 (*n*= 18) (*p*<0.05).

CONCLUSION: Risk factors such as difficult or incomplete cannulation and malignancy are considered as possible predisposing factors for complications. Age is an independent factor.

KEY WORDS: Endoscopic cholangiopancreatography, Risk factors

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is an invasive technique that combines the use of endoscopy and fluoroscopy to diagnose and treat certain

problems of biliary and pancreatic ductal system¹. As computerized axial tomography (CAT) and magnetic resonance imaging (MRI) have improved, ERCP has evolved from primarily a diagnostic procedure into primarily a therapeutic procedure. Endoscopic stent insertion, removal of stones, sphincterotomy and dilation of strictures are possible therapeutic procedures for ERCP. Besides various and major advantages of diagnostic and therapeutic application, ERCP carries high risk of mortality and morbidity. Therefore this approach must fulfill need and requirement of experienced and careful medical staff. The major risk of ERCP is development of acute pancreatitis, which can occur nearly in 5% of

Pervenuto in Redazione Giugno 2017. Accettato per la pubblicazione Settembre 2017

Correspondence to: Aylin Acar, M.D. Health Science University, Umraniye Training and Research, Hospital, Department of General Surgery, Umraniye, 3466 Istanbul, Turkey (e-mail: aylinacar79@hotmail.com)

the cases ². Bleeding and perforation are less common complications with major obstacles in diagnosis and treatment ³. Due to high risk of mortality and morbidity of these type of complications, knowledge of these factors may play an important role. For successful and safe ERCP procedures, provision of necessary laboratory conditions for pre-operative preparation, preparation of the procedural environment, and risk factor stratification should be performed as the first steps ⁴.

In the present study, our aim was to evaluate all patients undergoing ERCP procedure according to demographics, indications, ERCP findings, complications, and risk factors responsible for complications.

Material and Methods

We evaluated retrospectively patients who underwent ERCP during their hospitalization in Department of General Surgery. Informed consent was taken from all patients, and the study was approved by our hospital's Ethics Committee. ERCP procedures were applied by experienced gastroenterologists who perform more than 250 ERCP each year. Demographics, indications, ERCP findings, success rate, complications and the need of repeat procedure were evaluated with special emphasis on the difficulty in cannulation procedure, the primary etiology of the disease (benign/malign) and age. Blood sample was withdrawn from all patients after 8 and 24 hours following ERCP for hemogram and amylase. Abdominal pain accompanying high levels of amylase (>450 U/dL) was determined as acute pancreatitis; while asymptotically increased amylase (<450 U/dL) as hyperamylasemia, occurrence of melena or hematemesis or decreased levels of hemoglobin more than 3 gr/dL as bleeding, chills fever (>38 C) with abdominal pain and obstructive jaundice as cholangitis, and the presence of intra or retroabdominal air or radioopaque contrast in radiological studies with abdominal pain as perforation, respectively.

STATISTICAL ANALYSIS

Categorical variables were expressed as frequencies and percentages. Chi-square test was used for comparison of continuous parametric variables. The differences were considered statistically significant, if the p value was less than 0.05.

Results

Eighty-one patients were included in the study. A total of 112 ERCP procedure were performed. Thirty-eight patients (46.9%) were male and 43 (53.1%) were female. Mean age was 61.3 ± 14.17 (range, 17-88) and 31 patients

(38.3%) were seventy-years and older. Nineteen of these patients underwent ERCP two times and 5 cases underwent three times.

Final diagnosis according to our ERCP evaluations were as follows; 37 patients common duct stone (45.7%), 21 patients acute pancreatitis (25.9%), 11 patients malignancy (13.6%), 6 patients hydatid cyst (7.4%) and 6 patients cholangitis (7.4 %).

Selective cannulation of biliary ducts was successful in 68 patients (77.8%), and 5 of these (6.2%) was determined as difficult cannulation. We were unable to cannulate 13 cases (16%). Sixty-one cases were applied sphincterotomy (75.3%) and 12 (14.8%) received precut sphincterotomy. Stent was applied in 15 patients (18.5 %, 9 male and 6 female). Four of these stent-applied patients were 70-years and older (26.7%), and the remaining was below 70 (73.3%). Common duct stone was detected in 37 patients (45.7%) and 23 of these (62.2%) had cholelithiasis simultaneously.

Complications were detected in 28 patients following ERCP (34.6%). These patients were 13 male (46.4%) and 15 female (53.6%). Ten of them were 70 years and older (35.7%). Complication rate in patients 70 years and older was 32.2 % (n=10) compared to 35.3 % in patients younger than 70 (n= 18). According to our results, there was no statistical difference between the age groups ($p>0.05$). Patients with benign diseases showed less complications (21/70), in contrast to malignancy (7/11), (30 % vs. 63.6 %, respectively). There was statistical significance between these groups ($p=0.03$) (Table I). Complications are depicted in Table II. There was no perforation or mortality.

TABLE I - Malignancy and age above 70 versus complications

	Complication present		P*
	N	%	
Difficult or unsuccessful cannulation	9	69.2	0,001**
Malignancy	6	63.6	0.035**
Age above 70	10	32.2	0,735

*Pearson Correlation Test

**Correlation is significant at the 0.05 level (2-tailed)

TABLE II - Number of patients with complications

Complications	Number (n)	Percent (%)
Pancreatitis	7	8.6
Hyperamylasemia	15	18.5
Hemorrhage	5	6.1
Hemobilia	1	1.2
Perforation	0	0
Mortality	0	0

Nine cases with difficult or unsuccessful cannulation (69.2%) had complications. There was a statistical significance between difficult or unsuccessful cannulation and complication rates ($p=0.001$). In 3 cases out of 12 patients with pre-cut sphincterotomy (25%) and six cases out of 61 with sphincterotomy (9.8%), complications were seen ($p>0.05$).

There was no requirement for surgical procedures in complicated cases.

Discussion

ERCP is one of the most performed endoscopic procedures. It provides the treating physician with both diagnostic and therapeutic options. The recent shift towards interventional applications of ERCP is due to the emergence of advanced imaging techniques like ultrasound and MRI. Therefore, ERCP is currently utilized for therapeutic purposes⁵. With increasing number of ERCPs performed yearly, it is important that all medical staff involved in patients' treatment be well informed in indications, contraindications, benefits and alternatives to ERCP. Mainly ERCP is indicated for three disease categories: Biliary tract disorders, pancreatic diseases, and finally ampullary disorders.

Complications of ERCP are pancreatitis, bleeding, cholangitis and perforation⁶. The most common complication of ERCP is pancreatitis^{2,3,7}. Abdominal pain, elevation of serum amylase level and need for longer hospitalization is considered as pancreatitis. The mechanism of post-ERCP pancreatitis (PEP) remains unclear⁸. There are various publications reporting rate of pancreatitis between 0.8-45%⁹. Insufficient description of hyperamylasemia could be main reason for this difference. Hyperamylasemia following ERCP is related with pancreatic duct injury. Asymptomatic hyperamylasemia is more prominent as opposed to acute pancreatitis with incidence of 7.7% and 70% after ERCP¹⁰. In our study, rate of pancreatitis after ERCP was 8.6% and hyperamylasemia was 18.5 % in concordance with the literature.

Other important complications following ERCP are perforation, hemorrhage and cardiopulmonary disorders due to sedation. The most fatal complication after ERCP is perforation with incidence of 0.5%¹¹. In our study, there was no perforation and mortality. Bleeding usually occurs in 1-2 % of the patients during or after ERCP and is associated with 0.3 % mortality³. In half of the cases bleeding is present as late complication. Our rate of post-ERCP hemorrhage was 6.1 %, and hemobilia was 1.2 %. As pancreatic and biliary diseases are often combined with chronic diseases in older patients, ERCP is relatively more prone to entail complications in such patients than in younger. In practice, the overall complication rates of ERCP in patients aged 70 years and older are 5% to 8.7%, which is not as high as might be expected¹². Sugiyama and Atomi¹³ reported that there was

no difference in the post-ERCP frequency of pancreatitis in accordance with age. Kim et al¹⁴ found no statistical difference, but rather a reducing pattern of complications among older patients. Additionally, unexpected high rates of ERCP-related complications have been noted in younger patients in some other studies^{15,16}. Our present study supports Sugiyama et al.'s report, by showing no statistically difference between age and complication rates.

Endoscopic biliary cannulation during ERCP can fail¹⁷. Difficult cannulation and cases with precut sphincterotomy are accompanied with high incidence of post-ERCP complications^{5,18}. In our series, 9 cases with difficult or unsuccessful cannulation (69.2 %) had complications ($p=0.001$) in accordance with the literature. However, pre-cut sphincterotomy and sphincterotomy did not increase complication rates in our study ($p>0.05$). Similar to the increased rates of complications seen in patients with difficult cannulation, patients with malignancies in our series were shown to have higher complication rates (30 % vs. 63.6 %, respectively; $p<0.05$).

In conclusion, ERCP is an important invasive method in treatment of hepato-pancreaticobiliary diseases. True indications must pave the road for successful applications. Avoidance of unnecessary ERCP procedures is the best way to reduce complications. Clinicians must pay intensive attention to post-ERCP complications. Risk factors such as difficult or incomplete cannulation and suspected malignancy are considered as possible predisposing factors for complications, as shown in the current study. Age is an independent factor. Further studies with high numbers of patient load are needed to evaluate other possible risk factors and their effects on ERCP.

Riassunto

La colangiopancreatografia retrograde (ERCP) è una importante procedura sia diagnostica che terapeutica in pazienti affetti da patologie epato-bilio-pancreatiche. Con questo studio abbiamo inteso determinare nella nostra istituzione le cause predisponenti alle possibili complicazioni.

Si tratta di una analisi retrospettiva sui pazienti sottoposti ad ERCP tra Gennaio 2010 e Novembre 2011, prendendo in considerazione i dati demografici, le indicazioni alla procedura, i relativi referti, l'entità dei successi, le complicanze e la necessità di ripetere la procedura con particolare attenzione alle difficoltà di incannulazione, la natura benigna o maligna della patologia e l'età dei pazienti. Per l'analisi statistica è stato usato il Chi-quadro, considerando significative le differenze per il valore di $p < 0.05$.

La casistica riguarda un totale di 112 ERCP in 81 pazienti: 38 uomini (46.9%) e 43 donne (53.1%). L'età media dei pazienti è di 63,3 anni (da 17 a 88) e 31 pazienti sono di età superiore ai 70 anni (38,3%).

Le complicazioni si sono registrate in 28 pazienti (34,6%). In 9 casi (69,2%) con difficoltà o impossibilità di incannulamento si sono avute complicazioni ($p=0.001$).

I pazienti con patologia benigna hanno avuto minori complicazioni (21/70) in paragone con l'incidenza di complicazioni in quelli con patologia maligna (7/11): rispettivamente 30% vs 63,6%, con $p<0,05$.

L'incidenza di complicanze negli ultrasessantenni è stata del 32,2% ($n=10$) in paragone con il 35,3% di quelli di età inferiore ai 70 anni ($n=18$) con $p<0.05$.

In conclusione la difficoltà o impossibilità di incannulamento e la natura maligna della patologia rappresentano potenziali fattori predisponenti alle complicanze, mentre l'età rappresenta un fattore indipendente.

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