Impact of Coronavirus Pandemic on The Practice of ERCP: A Multicenteric Study

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Background and study aim: During COVID-19 pandemic majority of non-emergency endoscopic procedures has been deferred. ERCP is required to address both elective as well as emergency causes such as biliary obstruction with cholangitis. Our aim to explore the status of ERCP in different endoscopy units from different countries and to report the characteristics of patients presented to these units and their procedure details.

Patients and Methods: Representatives of main endoscopy units in different countries were invited to participate. Patient demographics, COVID-19 status, ERCP indications, laboratory findings, radiology findings, pre procedural preparation and post procedure complications were collected.

Results: Data of 352 patients from 11 countries were collected. Average age of patients was 57.80 (SD ±16.88) years and 182 (51.7%) were females. Majority of patient 332 (94.3%) did not have COVID-19 infection. Most centers reported a decrease in procedure volume, staff number and duration of ERCP procedure during COVID-19. The most common indications for ERCP were choledocholithiasis (51.7%) and suspected malignant biliary stricture (30.1%). Deep biliary cannulation was achieved in 324 (92%) cases. The most common therapeutic interventions carried out were CBD stone extraction. Complications were observed in 20 (5.6%) cases with bleeding being the most common immediate complication that was reported in 4.3% of patients. Post ERCP pancreatitis (PEP) was reported in 2.8% of cases and it was managed conservatively. The most common final diagnoses were choledocholithiasis (57.4%) and benign biliary strictures (10.8%).

Conclusion: COVID-19 pandemic negatively impacted ERCP procedure volume, training opportunities and was associated with decrease staff number and shorter procedure time.

INTRODUCTION

In December 2019, physicians from China reported clusters of pneumonia caused by a new coronavirus that could be isolated from infected patients **[1]**. An outbreak then began at the same time in Wuhan, China **[2]** the spread was rapidly escalating to which the World Health Organization declared a global pandemic on 11 March 2020. To date, the pandemic has spread across most countries in which the cumulative case number worldwide exceeding 46 million with 1.2 million reported deaths. The scale of the infection continues to expand and is unprecedented. Viral pneumonia affects about 200 million people every year, both children and adults **[3]**. Many respiratory viruses can cause severe form of pneumonia including coronavirus. The new corona virus, SARS-CoV 2 like severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS-CoV) presented predominantly with respiratory symptoms **[4,5]** gastrointestinal manifestations were less reported in SARS-CoV 2 compared to other coronaviruses **[6]**. Human to human transmission can occur mainly via droplets and direct contact with presumed high rates of hospital-related transmission **[7]**. Healthcare workers are more prone to infection than general population reaching up to 20% of diagnosed cases in a report from Italy and even more in initial reports from the unites states **[8,9]**. Several health care authorities including different gastrointestinal societies released recommendations to ensure protection of nosocomial transmission of infection to both healthcare workers and patient's **[9,10]**. Endoscopic procedures are now categorized as aerosol-generating procedures. Hence, healthcare workers (HCW) while performing endoscopic procedures are inevitably exposed to respiratory and GI secretions, therefore, adequate protection to HCW is important **[9,11-13]**. During COVID pandemic majority of the elective and non-urgent endoscopic procedures has been deferred, which has been broadly advocated by various societies. ERCP is an important therapeutic procedure that is required to address both elective as well as for several emergency causes such as biliary obstruction with cholangitis. However, this is also an aerosol-generating procedure, and these patients should also need to be managed with caution **[14-16]**. Also, there may be a grey area on the definition of what cases require an emergency or urgent ERCP according to a recent Survey **[17]**. The data to measure the impact of COVID-19 pandemic on ERCP performance is also limited **[18]**. The impact of different recommendations released by gastrointestinal societies needs to be continuously evaluated to confirm their effectiveness in preventing the spread of infection and to report its overall impact on service provided by different endoscopy unit. In this study, we aimed to explore the status of ERCP in different endoscopy units in different parts of the world, to report the characteristics of patients presented to these units and their procedure details.

PATIENTS AND METHODS

Retrospective observational study was conducted using data of ERCP patients between March and August 2020. The primary objectives of this study were to explore the change in performed ERCPs and to report patients and procedure characteristics inside gastrointestinal endoscopy units in response to COVID-19 in different countries. We used the below equation to calculate the sample size for assuming a confidence interval level of 95%:

$$n = [DEFF*Np(1-p)]/ [(d^2/Z^2_{1-\alpha/2}*(N-1)+p*(1-p)]$$

Calculated Sample size: 257 patients were required.

Representatives of main endoscopy units in different countries were invited to participate. A detailed data sheet covering all aspects of ERCP inside gastrointestinal endoscopy units was developed to collect information regarding patient demographics, COVID-19 status through asking patients about symptoms of COVID-19 and history of recent contact with COVID-19 patients, ERCP indications, routine, or urgent status (cholangitis or biliary leak), laboratory findings, radiology findings, pre procedural preparation and post procedure complications. All procedure were done using infection control measures according to WHO guidelines. All responses were collected in an online platform (RedCap) and data were analyzed anonymously to reveal the effect of SARS-CoV-2 pandemic on different aspects of ERCP practice in the studied endoscopy units.

Statistical analysis:

We used the Statistical package for social science SPSS (Release 22.0, standard version,

copyright © SPSS; 1989-02) to analyze the data. We performed a descriptive analysis and presented the results as mean ± standard deviation for quantitative variables and number (Percentage) for qualitative variables. Comparative analysis was done using independent t-test and Pearson's Chi-square test where applicable. All p-values were two-sided and considered as statistically significant if <0.05.

RESULTS

A total of 21 interventional gastrointestinal endoscopists participated in the study. They have collected data from 11 countries (Egypt, Brazil, Croatia, Philippines, Malaysia, Turkey, India, Morocco, Iran, USA and Pakistan) (Figure 1). Data of 352 patients were reported and analyzed. Average age of patients was 57.80 (SD ±16.88) years and 182 (51.7%) were females. Majority of patients were COVID-19 negative 332 (94.3%) whereas 2.8% were suspected cases and 0.9% were COVID-19 PCR positive, rest of baseline laboratory and radiological findings of the studied patients are described in **Table 1**. Patient with COVID-19 PCR positive was cured. The Approximately half (54%) of ERCPs were performed as an emergency procedure and 20.2% had previous ERCP done. Most centers reported a 50% decrease in staff number and duration of the procedure during COVID-19 in comparison to before COVID-19 practice. Most ERCP procedures were done by expert consultants and minority of the participating centers have involved trainees in ERCP procedures. The most common indications for ERCP were choledocholithiasis (51.7%) and suspected malignant biliary stricture (30.1%) rest of indications are presented in **Table 2**. Almost 68% of patients received antibiotics before ERCP. To PEP, only 85 (24.1%) received NSAIDs suppositories but half of them (55.1%) received hydration with ringer lactate or normal saline. Deep biliary cannulation was achieved in 324 (92%) cases mainly using conventional papillotomy over the guidewire (75.3%). However, freehand needle knife fistulotomy or sphincterotomy was used in 34 (9.7%) cases. Sphinceterotomy was performed in 255 (72.4%) cases which were limited Sphinceterotomy in 138 (54.1%) cases. Sphincteroplasty was performed in a few patients (11.9%) for 1±1.05 minutes. The average diameter of the balloon used for dilation was 13.5±2.3 mm. Occlusion cholangiogram was performed in 57.4% of cases. The most common therapeutic interventions carried out were CBD stone extraction using retrieval balloon in 160 (45.5%) of cases followed by plastic stent 158 (44.9%). Rest of ERCP procedure details and interventions are presented in **Table 3**. Biopsies were performed in 58 cases and revealed adenocarcinoma in 43 cases (74.13%). Cholangiocarcinoma was the diagnosis in 2 cases (3.44%) while 4 cases were suspected to be malignant (6.88%). Of note, no malignant cells were observed in 9 cases (15.5%). Complications were observed in 20 (5.6%) cases with bleeding being the most common immediate complication that was reported in 4.3% of patients. PEP was reported in 2.8% of cases and it was managed conservatively. Four patients (1.13%) had delayed post ERCP bleeding that was controlled with medical therapy and adrenaline injection. One patient (0.28%) with delayed post ERCP bleeding died after leaving the hospital against medical advice. Eight patients (2.3%) were referred to interventional radiology, 24 were referred for surgery (11.9%) and 18 patients (5.1%) were referred for endoscopic ultrasound for further management. The most common final diagnoses were choledocholithiasis (57.4%) and benign biliary strictures (10.8%) **(Table 4).**

Table 1: Laboratory and Radiological Findings of the Study Population (n=352)

Variables	Mean ±SD or n(%)
Hemoglobin (mg/dl)	12.65±3.15
WBC 10^9/L	7.89±4.44
Total Bilirubin (mg/dl) (median)	6.0(0.2-49)
AST (median, range) U/L	80 (11-550)
ALT (median, range) U/L	97(12-935)
GGT (median, range) U/L	295(4-5717)
Alkaline phosphatase (median, range) U/L	295(32-5717)
INR %	1.12(1-12)
Serum creatinine mg/dl (median, range)	0.9(0.3-9.41)
Amylase	70.5(4-3762)
Lipase	71.5(6-13248)
CEA	3.08 (1.8-2230)
CA 19-9	169.4(1.3-120000)
AFP	2.6(1-20)
Diagnostic Imaging Modality Used:	
Ultrasound	195(55.4)
CT scan	112(31.8)
MRCP	108(30.7)
EUS	18(5.1)
Findings on imaging:	
CBD size (in mm)	12.7±5.8
IHBR dilatation	259(73.6)

SD, standard deviation; WBC, white blood cells; mg/dl, milligrams per deciliter; AST, aspartate aminotransferase; ALT, alanine aminotransferase; U/L, unit per liter; GGT, gamma-glutamyl transferase; INR, international normalized ratio; CEA, carcinoembryonic antigen; CA 19-9, carbohydrate antigen 19-9; AFP, alpha-fetoprotein; CT, computed tomography; MRCP, magnetic resonance cholangiopancreatography; EUS, endoscopic ultrasound; CBD, common bile duct; IHBRD, intrahepatic biliary radicle dilation.

Table 2: Indication of ERCP During COVID-19 Pandemic.

Indication	Frequency	Percent
Biliary Stones	182	51.7
Pancreatic Stones	3	.9
Benign stricture	12	3.4
Malignant stricture	106	30.11
Indeterminate stricture	10	2.8
Post-transplant stricture	4	1.1
Biliary Stent removal/change	22	6.3
Biliary Leak/fistula	3	.9
Pancreatic Stent removal/change	1	.3
Other	9	2.6
Total	352	100.0

ERCP, Endoscopic retrograde cholangiopancreatography; COVID-19, coronavirus disease 2019.

Table 3: ERCP Techniques Used and Interventions Performed.

Variables	Mean ±SD or n (%)
Deep duct cannulation was done using:	
• Conventional papillotomy over the guidewire	265 (75.3)
• Conventional cannula	26 (7.4)
• Freehand Needle knife fistulotomy or sphincterotomy	34 (9.7)
• Double guidewire technique	6 (1.7)
• Pancreatic precut	1 (0.3)
• Rendezvous technique	1 (0.3)
• EUS guided	1(0.3)
Intervention done:	
• CBD stone extraction: using Retrieval balloon	160 (45.5)
• CBD stone extraction: using Dormia basket	7 (2.0)
• Plastic Stent insertion	158 (44.9)
• Metal Stent insertion	33 (9.4)
• Pancreatic duct stenting	6 (1.7)
• Dilating of a stricture	13 (3.7)
• Stent removal	32 (9.1)
Other procedures:	
• Brush cytology	23 (6.5)
• Biopsies	58 (16.33)
• Ampullary biopsy	11 (3.1)
• Cholangioscopy	1 (0.3)

ERCP, Endoscopic retrograde cholangiopancreatography; SD, standard deviation; EUS, endoscopic ultrasound; CBD, common bile duct.

Table 4: Final Diagnosis for Patients Undergoing ERCPs During COVID-19 Pandemic

Choledocholithiasis (with combined cystic dilations of CBD n=4)	202
Benign biliary strictures	38
Malignant biliary strictures	33
Normal cholangiography	6
Pancreatic tumor	19
Primary sclerosing cholangitis	6
Papillary adenocarcinoma	9
Biliary cast syndrome	3
Pancreatic ductal adenocarcinoma	4
Post liver transplant leakage and strictures	2
Acute pancreatitis	2
Missing	28

DISCUSSION

In modern human history, infectious diseases have posed a threat to public health several times, coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has emerged as a global public health crisis. ERCP is well recognized as an important therapeutic modality for biliary and pancreatic pathology. ERCP is the first-line modality for management of choledocholithiasis **[19]**, decompression of pancreatic or biliary strictures **[20]** and for evaluation and/or treatment of proximal biliary neoplasia **[21]**. First case of novel corona virus disease (COVID-19) was reported within Wuhan, a capital city of Hubai Province, China in November 2019 and it was declared as pandemic by WHO in March 2020 **[22,23]**. Covid-19 is acting as a double edge sword, increasing direct burden on health care system on one hand and affecting health care providers leading to reduced work force on the other hand **[24]**. Different countries around the globe had different response time and adopted different steps in order to contain covid-19 and slow down it's spread within their boundaries with variable degree of success **[25]**. Globally this pandemic had a significant impact on endoscopies practices with around 83% reduction in volumes **[26]**.

Similar overall reduction has seen in nationwide multicentric Italian study as well as cross sectional study by Muhammad Uzair et al **[27,28]** but there is no reduction in number of urgent cases of ERCP procedure **[27]**. Although COVID-19 has disturbed scheduled patients, we analyzed data of 352 patients from various endoscopy units from 11 different countries and there was significant reduction in the total number of procedures. Approximately half (54%) of the ERCPs were performed as an emergency procedure, and this was related to postponement of most non-urgent cases. The commonest indications before COVID-19 pandemic were choledocholithiasis and malignant strictures **[29,30]**. In our study, commonest indication remained the same with biliary stones (51.7%) leading to cholangitis followed by malignant strictures (30.11%) being the commonest indications. Various international organizations including British society of gastroenterology have given guidance on appropriate precautions regarding this aerosol generating endoscopic procedure **[31,32]**. Voon Merg Leow et al shared their experience of doing ERCP during COVID-19 era by using large aerosol protective barrier for ERCP [33]. Another technique explained by Jing Zhongwee from Singapore where use of transparent barrier enclosure box over patient's head and upper torso while performing ERCP [34]. In our study, procedures were performed after taking all necessary precautions. Majority of patients were COVID-19 negative reflecting the meticulous screening and triage of patients before ERCPs. Achieving deep cannulation remains a substantial barrier to success in ERCP, It has been suggested that expert endoscopists are expected to perform at a 95% to 100% technical success level **[35]**. In our study, deep biliary cannulation was achieved in 92% of patients. So, the deep biliary cannulation was not markedly affected by COVID-19 pandemic. The reported rate of bleeding related to ERCP is approximately 1 to 2 percent **[36-38]**. Our cohort demonstrated that immediate bleeding was experienced in 4.3% of the patients which is higher than previous reported studies before COVID-19 pandemic. Our data showed that perforation was reported in 0.6% of the patient, similar findings were reported in the previous systematic survey of prospective studies before COVID-19 pandemic **[39]**. Pancreatitis were reported in 2.8% in our study, and this was in agreement with previous studies before COVID-19 pandemic **[37,40,41]**. So, there is no effect of COVID-19 pandemic on the percentage of perforation and post ERCP pancreatitis. It is important to highlight that this pandemic not only affected endoscopic procedure volume but also the training of gastroenterology fellows and nurses within endoscopy units **[42]**. Raising the concern whether COVID-19 pandemic affects procedure time and staff number, approximately, there was a 50 % decrease in staff members during COVID-19 pandemic and this was implemented to reduce exposure of health worker to COVID-19. Same findings reported by many studies **[43-45]**. Our data demonstrate that there is a considerable reduction in procedure time during COVID-19 pandemic compared to before pandemic time this is explained by choice of experienced endoscopists rather than less experienced endoscopists or trainee. It is worth mentioning that decreasing number of procedures, shift of gastroenterologists to COVID-19 wards, decreasing number working staff in gastrointestinal endoscopy units and use of full PPE can increase the cost of ERCP procedures during COVID-19 pandemic and can impact the chances available for training of fellows. Limitations to this study include small number of participating centers that needs to be increased in future studies. One more limitation is lack of involvement of less experienced endoscopists or trainee who may have an impact on procedure time. It is important to resolve barriers preventing fellows from having their regular training in ERCP by meticulous pre procedure triage of patients, proper choice of patients and adequate use of personal protective equipment. In conclusion, COVID-19 pandemic negatively impacted ERCP procedure volume, training opportunities and was associated with decrease staff number and shorter procedure time.

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Ethical considerations: The study protocol conforms with the ethical guidelines and standards of the Declaration of Helsinki and it was approved by Institutional Review Board at the National Liver Institute, Menoufia University, Egypt (reference number: 00203/2020).

HIGHLIGHTS

1- COVID-19 pandemic markedly impacted all gastrointestinal (GI) endoscopic procedures.

2- Although procedure volume and chance of training for fellows were decreased, many GI endoscopy centers continued to offer ERCP to address biliary obstruction with cholangitis.

3- The most common indications for ERCP were choledocholithiasis and suspected malignant biliary stricture and the most common therapeutic interventions carried out were CBD stone extraction.

4- Complications were observed in 5.6% of cases with bleeding being the most common immediate complication in 4.3% of patients followed by PEP in 2.8% of cases.

5- The most common final diagnoses were choledocholithiasis (57.4%) and benign biliary strictures (10.8%).

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