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Impact of the COVID-19 pandemic on endoscopic retrograde cholangiopancreatography: a single center experience

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Yousef M: data collection, obtaining Ethical Committee approval. Osman H: data collection, initial drafting. Abdel-Gawad M: statistical analysis. Elsayed M and Sapra A: manuscript writing, data collection, study design. Ozawa E: final revision, editing and approval for submission.

Conflict of interest: the authors declare no conflict of interest.

Ethical Clearance: a written informed consent was obtained from all patients included and the study

protocol was approved by the Ethical Committee and Institutional Review Board of Qena Faculty of Medicine, South Valley University, Qena, Egypt, in February 2021 and assigned the number: SVUMEDMED0184212128.

ABSTRACT

Background: the COVID-19 pandemic has impacted on several aspects of health care services worldwide. The aim of the study was to determine its influence on the case volume, success rate and complication rate of endoscopic retrograde cholangiopancreatography (ERCP).

Method: all patients who underwent ERCP one-year before and after applying COVID-19 safety measures at the Qena University Hospital were included. Data were collected from the patients' records, analyzed and compared.

Results: a total of 250 patients underwent ERCP between April 1st, 2019 and March 31st, 2021, and the mean age of participants was 52 ± 18 years. There was a 5 % increase in case volume after applying COVID-19 safety measures (128 vs 122) and the total procedure time was significantly shorter (42 vs 46 minutes, $p = 0.04$). There was no significant difference in the overall success rate and complication rate. Procedure success significantly correlated with cannulation attempts and total procedure time in both groups, and serum bilirubin and cannulation time in the pre-COVID-19 patients and alkaline phosphatase (ALP) in post-COVID patients. ERCP-related complications significantly correlated with cannulation attempts in both groups, and ALP, international normalized ratio (INR), cannulation time and total procedure time in pre-COVID-19 patients, and platelet count and amylase in post-COVID patients. Two patients were confirmed COVID-19 cases at the time of ERCP; therapeutic targets were achieved in both with a smooth post-ERCP recovery. Three out of nine ERCP team members caught a mild to moderate COVID-19 infection and recovered after receiving proper management.

Conclusion: our result show that there was no negative impact of using COVID-19 safety measures and precautions on the case-volume, indications, overall outcome or complication rate of ERCP.

Keywords: ERCP. COVID-19. Biliary obstruction. Personal protective equipment.

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is an advanced endoscopic procedure with a wide spectrum of indications including calcular and malignant biliary obstruction, iatrogenic and inflammatory biliary strictures and post-cholecystectomy bile duct injuries (1-4). Different technical steps and endoscopic instruments are used to achieve the therapeutic target, and several ERCP-related complications such as pancreatitis, bleeding, perforation and cholangitis are reported worldwide. The success rate and complication rate vary greatly from center to center according to the endoscopist experience, volume of cases, indications, cannulation technique and many other factors (5-8).

COVID-19 is an infectious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus which was detected in November 2019 and declared a global pandemic in March 2020 by the World Health Organization (WHO) (9,10). Clinical manifestations of COVID-19 infection may include fever, cough, myalgia, fatigue and dyspnea. However, around 80 % of infected patients remain asymptomatic (11,12). The SARS-CoV-2 virus has a very high infectivity and spread rate that can occur during the incubation period, and healthcare workers are up to three times more vulnerable to infection than the general population (13).

The pandemic has represented a unique challenge to all clinical services, including endoscopy, with its severity, virulence and unpredicted clinical course (14). Several infection-control measures have been added to the routine ones in order to minimize the risk of virus transmission to patients and endoscopy staff during gastrointestinal endoscopy (15-17). There is no doubt that these extraordinary measures have led to hard communication among the work team and an additional workload that might influence the success and overall outcome of endoscopic procedures.

The aim of the present study was to analyze the influence of the COVID-19 pandemic on the case volume, success rate and complication rate of ERCP at Qena University Hospital.

PATIENTS AND METHOD

All patients that underwent an ERCP procedure at Qena University Hospital between April 1st, 2019 and March 31st, 2021 were retrospectively included. Patients were classified into two groups, before and after applying COVID-19 safety precautions (between April 1st, 2019-March 31st, 2020 and between April 1st, 2020-March 31st, 2021, respectively). Data from patients' records including indications, technical steps, procedure outcome, complications and hospital admission were collected, analyzed and

compared.

Statistical analysis

Data were collected from patients' records and then analyzed using the Statistical Package for the Social Sciences (SPSS version 20, IBM and Armonk, NY, USA). Continuous variables were expressed as the mean \pm SD or median and range according to type. Nominal variables were expressed as frequencies and percentages. The Chi-squared test was used to compare nominal data and Mann-Whitney test to compare non-parametric data. Level of confidence: 95 % and p-value $<$.05 was considered as significant.

RESULTS

A total of 250 patients underwent an ERCP procedure in our center between April 1st, 2019 and March 31st, 2021. The mean age was 52 ± 17.8 and 154 were female (61.6 %). The overall procedure success rate was 93 % and the overall complications rate was 7 %, the remaining baseline characteristics and ERCP procedure-related data are presented in table 1.

Different indications for the ERCP procedures are presented in figure 1. The most frequent indications that represented about 95.4 % of cases were common bile duct stones (CBDS), cholangiocarcinoma (CCA), pancreatic head mass/cyst and post-cholecystectomy CBD injury. Other indications, including gallbladder cancer, papilla of Vater adenocarcinoma, sphincter of Oddi dysfunction, hepatocellular carcinoma, migrating stent, acute on top of chronic pancreatitis, primary sclerosing cholangitic stricture and indeterminate distal CBD stricture, represented about 5.6 % of cases.

By April 1st, 2020, the COVID-19 pandemic prevention and protection measures were adopted in our center. We recommended a stepwise preadmission screening protocol including questionnaire triage and a thorough clinical assessment of all patients, chest computed tomography (CT) in patients with positive questionnaires or suspicious clinical findings, and then confirmatory nasopharyngeal swabs in patients with positive chest CT findings. Personal protective equipment (PPE) was used by endoscopy staff, including surgical masks, head covers, face shields, gowns, gloves and boots. Special masks (mainly N95) and eye goggles were only used in confirmed COVID-19 cases. The PPE used for patients were surgical masks, gowns and head covers. All procedures were performed in the routine endoscopy room as a negative pressure room was unavailable. Regardless of their COVID-19 status, all patients

underwent the ERCP procedure under general anesthesia with endotracheal intubation and underwent a routine post-ERCP follow up for 24 hours.

Table 2 shows about a 5 % increase in the volume of cases from 122 cases before COVID-19 to 128 after COVID. The comparison between the two groups showed statistically significant better platelet counts and INR and higher pancreatic amylase level in patients before COVID-19. The rest of variables showed statistically insignificant differences between the two groups. Regarding procedure-related data, there was statistically significant shorter total procedure time in patients after COVID-19 (42 vs 46 minutes, $p = 0.04$) while other variables including indications, CBD diameter, cannulation technique, cannulation attempts, cannulation time, overall success rate and complication rate showed statistically insignificant differences (Table 3).

Both cannulation attempts and total procedure time showed a statistically significant correlation with procedure success in both groups, while serum creatinine, serum bilirubin and cannulation time showed a statistically significant correlation with procedure success in patients before COVID-19 and alkaline phosphatase showed a statistically significant correlation in patients after COVID-19. The rest of variables are shown in table 4.

Table 5 shows statistically significant correlations between ERCP-related complications and alkaline phosphatase (ALP), INR, cannulation attempts, cannulation time and total procedure time in patients before COVID-19 and with cannulation attempt, platelets count and pancreatic amylase in patients after COVID-19. Two of the included patients had a confirmed COVID-19 infection at the time of ERCP, two 69 and 80-year-old females with a pancreatic head mass compressing the CBD. ERCP procedures were performed under safety precautions and biliary access was achieved via transpapillary fistulotomy (TPF) because of failed trials with wire-guided cannulation (WGC). Then, a biliary stent was deployed during a total procedure time of 39 and 46 minutes, respectively, with a smooth post-procedure course. On the other hand, three out of nine ERCP team members caught a mild to moderate COVID-19 infection and fully recovered after receiving the proper management via home isolation.

DISCUSSION

Gastrointestinal endoscopic procedures are known as high and moderate-risk procedures for COVID-19 infection because of the presence of the causative virus in nasopharyngeal secretions and stool samples,

respectively (18,19). Subsequently, certain safety measures become necessary to keep the quality standard of endoscopic procedures in the era of COVID-19 pandemic, including the use of PPE to help protect patients and health care providers, and requesting certain investigations such as chest CT and/or nasopharyngeal swab to help detect patient at high risk of COVID-19 (19). Health authorities have put many restrictions on medical practice, including endoscopy, for several reasons, including saving resources for COVID-19 patients and reducing the risk of infection.

A previous study (20) about the impact of the COVID-19 pandemic on endoscopy services and bowel cancer screening in comparison to the pre-COVID era concluded that there was a substantial reduction in the average weekly activity of colonoscopy (90 %), flexible sigmoidoscopy (91 %) and upper endoscopy (86 %), whereas the reduction was only 44 % for ERCP procedures. In a web-based survey (21) of 55 countries, there was an average 83 % reduction in total endoscopy volumes during the COVID-19 pandemic. Interestingly, there was a small increase in the volume of ERCP cases during the COVID period and the same study (21) showed a relative increased volume of upper and lower endoscopies in Oceania during the pandemic.

In another survey of 31 endoscopy centers located in Northern and Central Italy (22), data were retrospectively collected from a total of 804 patients who underwent ERCP for different indications. There was about a 44 % reduction in case volume in the same period (from 1,439 in 2019 to 804 in 2020). Only 22/804 procedures (2.7 %) were performed in SARS-CoV-2-positive patients and only 2/128 procedures (1.5 %) were performed in confirmed COVID-19 cases in our study. The overall complication rate and procedure-related deaths in our center were less than in the Italian study (about 6 % vs 7 % and 0 % vs 0.5 %, respectively). These findings can be attributed to the younger age of the patients included in our study and also the different indications for ERCP, as malignant biliary obstruction was the most common indication for ERCP in the Italian study in contrast to calculi obstruction in our study. As screening protocols vary from country to country and from one area to another according to the available resources and expertise, the most commonly used screening protocols in previous multicenter studies were questionnaire triage in all centers, nasopharyngeal swab in 96.8 % and chest computed tomography in 76.7 % of the included centers. In our center, questionnaire triage and clinical assessment were used for all patients, chest CT in patients with a positive questionnaire and/or clinical suspicion, while the nasopharyngeal swab was only used for patients with CT positive findings.

Comparison between the use of standard PPE and enhanced PPE in the two groups of patients who underwent ERCP before and after the COVID-19 pandemic was performed in a previous study (23) that initially proposed a negative effect of using extraordinary infection control measures on the overall outcome of ERCP procedures. However, there were no statistically significant differences between the two groups of patients regarding technical success rate, cannulation success rate, cannulation times, number of cannulation attempts, adverse events and length of hospital stay. Despite the reasonable number of patients in both groups (93 vs 128), the indication for ERCP was calculic biliary obstruction in 88.7%. In our study, malignant indications represented collectively about 34% vs 57% for calculic obstruction. It is worth mentioning that the ERCP procedure is more technically demanding and time consuming in malignant biliary obstruction, which might lead to a more negative impact of using enhanced PPE on the endoscopist's decision and communication among the team members.

In agreement with our findings, previous studies (23-25) have concluded that there was no statistically significant change in the number of ERCP procedures before and after the COVID-19 pandemic. This conclusion could be attributed to the emergency indications of most ERCP procedures. A survey study (26) that included 11 large centers reported several urgent indications that require endoscopic interventions across all centers during the pandemic, including gastrointestinal bleeding, gastrostomy tube placement and biliary drainage for obstructive jaundice and cholangitis. In another multicenter international case-control study of 16 confirmed COVID-19 infected patients who underwent 18 ERCP procedures, technical success was significantly lower in COVID-19 cases in comparison to controls (14/18 vs 64/67, $p = 0.034$). However, the difference in the rate of procedure-related adverse events was not significant (1/18 vs 10/67, $p = 0.44$) (27). Our study included only two COVID-19 confirmed cases, both had malignant biliary obstruction and underwent ERCP procedures with a successful biliary drainage and no reported complications.

A retrospective analysis of the outcome of an advanced endoscopic procedure that was mainly performed on an urgent basis was performed. This study reflected our center's experience in the use of safety measures and precautions within the available resources in the era of COVID-19 pandemic that impacted on all aspects of the health services worldwide. In conclusion, there was no negative impact of using COVID-19 safety measures and precautions on the case-volume, indications, overall outcome or complication rate of ERCP in our center.

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Table 1. Baseline criteria of the included patients (n = 250)

<i>Variable (n = 250)</i>	<i>Mean ± SD (range)</i>
Age (year)	52 ± 17.8 (11-90)
Female (number and percent)	154 (61.6 %)
Creatinine (mg/dl)	1 ± 0.7 (0.1-5.6)
Total bilirubin (mg/dl)	9.4 ± 8.5 (0.7-43)
Direct bilirubin (mg/dl)	8 ± 7.7 (0.3-39.8)
INR	1.1 ± 0.3 (0.7-4)
Hb (g/dl)	12.2 ± 1.4 (7.8-16)
WBCs (x 10 ³)	9.9 ± 4.8 (3.7-23.7)
Platelets (x 10 ³)	259 ± 93.9 (27-701)
ALT (U/l)	160.8 ± 135.4 (22-900)
AST (U/l)	144.3 ± 121.1 (19-759)
ALP (U/l)	388.6 ± 420 (38-3,329)
Pancreatic amylase (U/l)	97.2 ± 141 (19-1,746)
CBD diameter (mm)	12.33 ± 3.6 (4-26)
Cannulation time (minutes)	5.8 ± 8.5 (1-52)
Number of cannulation attempts	2.5 ± 2.1 (1-12)
Procedure time (minutes)	49.8 ± 23.1 (15-243)
Overall success (number and percent)	232 (93 %)
Overall complications (number and percent)	17 (6.8 %)

INR: international normalized ratio; ALT: alanine transaminase; AST: aspartate transaminase; ALP: alkaline phosphatase; CBD: common bile duct.

Table 2. Comparison between the two groups regarding baseline variables

<i>Variable</i>	<i>Before COVID-19</i> <i>(n = 122)</i>	<i>During COVID-19</i> <i>(n = 128)</i>	<i>Significance</i>
Age (year)	55	56	0.815
Female (number and percent)	79 (64.7 %)	75 (58.6 %)	0.3
Total bilirubin (mg/dl)	6.6	6.8	0.616
Direct bilirubin (mg/dl)	5.4	5.7	0.527
INR	1	1.1	0.036
Hb (g/dl)	12.1	12.1	0.914
WBCs (x 10 ³)	7.9	8	0.555
Platelets (x 10 ³)	279	238	0.014
ALT (U/l)	102	116	0.238
AST (U/l)	97	105	0.361
ALP (U/l)	317	314	0.381
Pancreatic amylase (U/l)	71	68	0.002
Creatinine (mg/dl)	0.9	0.9	0.36

Data presented as medians except female gender that is presented as number and percentage. INR: international normalized ratio; ALT: alanine transaminase; AST: aspartate transaminase; ALP: alkaline phosphatase; CBD: common bile duct.

Table 3. Comparison between the two groups regarding ERCP-related variables

<i>Variable</i>	<i>Before COVID-19 (n = 122)</i>	<i>During COVID-19 (n = 128)</i>	<i>Significance</i>
Indications			
CBDS	71	72	0.077
CCA	24	26	
Ph mass/cyst	16	20	
Post-surgical CBD injury	4	3	
Others	7	7	
CBD diameter (mm)	12	13	0.324
Cannulation time (minutes)*	3	2	0.051
Number of cannulation attempts*			
1	59	64	
2	13	7	
3	16	30	0.066
4 or more	31	25	
Total procedure time (minutes)	46	42	0.044
Overall success rate (number and percent)	113 (92.6 %)	119 (92.9 %)	0.9
Overall complication rate (number and percent)	9 (7 %)	8 (6 %)	0.723

CBD diameter and total procedure time are presented as the median; the rest of variables are presented as a number and percentage. *Cases with failed duodenal intubation were excluded (three before and two after COVID-19). CBDS: common bile duct stones; CCA: cholangiocarcinoma; Ph: pancreatic head.

Table 4. Correlation between procedure success and different variables in both groups

<i>Variables</i>	<i>Before COVID-19 (n = 122)</i>		<i>During COVID-19 (n = 128)</i>	
	Pearson correlation	Significance (2 tailed)	Pearson correlation	Significance (2 tailed)
Age (year)	0.154	0.552	-0.093	0.297
Female (number and percent)	-0.063	0.319	0.017	0.849
Creatinine (mg/dl)	-0.259	0.004	0.068	0.443
INR	-0.157	0.084	-0.136	0.126
Bilirubin (mg/dl)	-0.234	0.010	-0.001	0.989
D. bilirubin (mg/dl)	-0.239	0.008	0.025	0.776
ALT (U/l)	0.035	0.705	0.158	0.074
AST (U/l)	-0.017	0.850	0.143	0.106
ALP (U/l)	-0.079	0.386	-0.212	0.016
Hb	0.173	0.056	0.248	0.127
WBCs (x 10 ³)	-0.099	0.280	0.153	0.085
Platelets (x 10 ³)	0.006	0.949	0.082	0.356
Amylase (U/l)	-0.028	0.762	0.045	0.610
CBD diameter (mm)	-0.058	0.525	0.152	0.086
Number of cannulation attempts	-0.206	0.025	-0.366	0.000
Cannulation time (minutes)	-0.262	0.004	-0.092	0.313
Procedure time (minutes)	-0.184	0.042	-0.200	0.024

INR: international normalized ratio; ALT: alanine transaminase; AST: aspartate transaminase; ALP: alkaline phosphatase; CBD: common bile duct.

Table 5. Correlation between procedure-related complications and different variables in both groups

<i>Variables</i>	<i>Before COVID-19 (n = 122)</i>		<i>During COVID-19 (n = 128)</i>	
	Pearson correlation	Significance (2 tailed)	Pearson correlation	Significance (2 tailed)
Age (year)	-0.075	0.413	-0.159	0.073
Female (number and percent)	0.011	0.902	0.086	0.334
Creatinine (mg/dl)	-0.114	0.211	-0.041	0.644
INR	0.269	0.003	-0.070	0.435
Bilirubin (mg/dl)	-0.092	0.316	-0.093	0.294
D. bilirubin (mg/dl)	-0.100	0.275	-0.093	0.294
ALT (U/l)	-0.065	0.478	-0.055	0.534
AST (U/l)	-0.041	0.654	-0.050	0.578
ALP (U/l)	0.313	0.000	-0.058	0.514
Hb	0.134	0.140	0.034	0.700
WBCs (x 10 ³)	0.061	0.505	-0.159	0.073
Platelets (x 10 ³)	0.054	0.558	0.191	0.031
Amylase (U/l)	0.026	0.774	0.248	0.005
CBD diameter (mm)	-0.159	0.080	-0.112	0.210
Cannulation attempts	0.396	0.000	0.220	0.013
Cannulation time (minutes)	0.418	0.000	0.178	0.050
Procedure time (minutes)	0.387	0.000	0.083	0.71

INR: international normalized ratio; ALT: alanine transaminase; AST: aspartate transaminase; ALP: alkaline phosphatase; CBD: common bile duct.

Fig. 1. Different indications in all procedures performed (n = 250). Others include gallbladder cancer, papilla of Vater adenocarcinoma, sphincter of Oddi dysfunction, hepatocellular carcinoma, migrating stent, acute on top of chronic pancreatitis, primary sclerosing bile duct stricture and indeterminate distal CBD stricture.

Accepted Article