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Impact of COVID-19 Pandemic on Endoscopic Retrograde Cholangiopancreatography; A Single Center Experience

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Keywords:

ERCP; COVID-19; Biliary Obstruction; Personal Protective Equipment

List of Abbreviations:

Abbreviation	Meaning
COVID-19	Coronavirus Disease of 2019
ERCP	Endoscopic Retrograde Cholangiopancreatography
CBD	Common Bile Duct
CBDS	Common Bile Duct Stone (s)
PPE	Personal Protective Equipment
CT	Computerized Tomography

Conflict of Interest:

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Nothing to disclose

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Ethical Clearance:

An informed written consent has been obtained from all included patients and the study protocol was approved by 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

COVID-19 pandemic has impacted several aspects of health care services worldwide. Our aim was to study its influence on the case volume, success rate and complication rate of ERCP.

Method

All patients who underwent ERCP one-year before and after applying COVID-19 safety measures at Qena university hospital were included. Data were collected from the patients' records, analyzed and compared.

Result

A total of 250 patients were subjected to ERCP between April 1, 2019 and March 31, 2021, mean age 52±18. There was 5% increase in case volume after applying COVID-19 safety measures than before (128 vs 122) and the total procedure time was significantly shorter (42 versus 46 minutes, p=0.04). The overall success rate and complication rate showed no significant difference. Procedure success significantly correlated to cannulation attempts and total procedure time in both groups, and serum bilirubin and

cannulation time in patients before COVID-19, and ALP in patients after. ERCP related complications significantly correlated with cannulation attempts in both groups, and ALP, INR, cannulation time and total procedure time in patients before COVID-19, and platelets count and amylase after. Two patients were confirmed COVID-19 cases at the time of ERCP, therapeutic targets were achieved in both with smooth post-ERCP recovery. Three out of 9 ERCP team members have caught mild to moderate COVID-19 infection and recovered after receiving proper management.

Conclusion

Our result showed no negative impact of using COVID-19 safety measures and precautions on the case-volume, indications, overall outcome or complication rate of ERCP.

Introduction:

Endoscopic retrograde cholangiopancreatography (ERCP) is an advanced endoscopic procedure with a wide spectrum of indications includes 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 utilized to achieve the therapeutic target, and several ERCP-related complications like pancreatitis, bleeding, perforation and cholangitis are reported worldwide. It is worth notice that 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 has been detected in November 2019 and declared by WHO as a global pandemic in March 2020 **(9,10).** Clinical manifestations of COVID-19 infection may include fever, cough, myalgia, fatigue, and dyspnea, however; about 80% of infected peoples remain asymptomatic **(11,12)**. SARS-CoV-2 virus has a very high infectivity and spread 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 coarse **(14)**. Several infection-control measures have been added to the routine ones in order to minimize the risk of virus transmission to patients and to endoscopy staff during gastrointestinal endoscopy **(15-17).** There is no doubt that these extra-ordinary measures have led to hard communication among the work-team and additional workload that might influence endoscopic procedures' success and overall outcome.

Aim:

To study the influence of COVID-19 pandemic on the case volume, success rate and complication rate of ERCP at Qena university hospital.

Patients and Method:

Patients

All patients subjected to ERCP procedure at Qena university hospital between April 1, 2019 - March 31, 2021, were retrospectively included. The included patients were classified into two groups, before and after applying COVID-19 safety precautions (between April 1, 2019- March 31, 2020, and between April 1, 2020- March 31, 2021, respectively). Data from patients' records including indications, technical steps, procedure outcome, complications and hospital admission were collected, analyzed, and then compared.

COVID-19 Safety Measures

By April 1, 2020, COVID-19 pandemic prevention and protection measures have been adopted in our center. We recommended a stepwise preadmission screening protocol including questionnaire triage and thorough clinical assessment of all patients, chest CT in patients with positive questionnaire or suspicious clinical findings, and then confirmatory nasopharyngeal swab in patients with positive chest CT findings. Personal protective equipment (PPE) were used by endoscopy staff including surgical mask,

overhead, face shield, gowns, gloves and boot. Special mask (mainly N95) and eye googles were used only in confirmed COVID-19 cases. The used PPE for patients were surgical mask, gown and overhead. All procedures were done in the routine endoscopy room as negative pressure room was unavailable. Regardless their COVID-19 status, all patients were subjected to ERCP procedure under general anesthesia with endotracheal intubation and undergone a routine post-ERCP follow up for 24 hours. One of the intended aims of our center's safety measures was to decrease the contact time between the endoscopy team staff each other's and between them and the patients, this aim enforced us to hold training program on time-consuming endoscopic procedures like ERCP and make all endoscopic accessories expected to be used available before starting the procedure.

Statistical Analysis

Data were collected from patients' records and then analyzed using Statistical Package for the Social Science (SPSS version 20, IBM and Armonk, NY, USA). Continuous variables were expressed in form of mean±SD or median and range according to its type. Nominal variables were expressed as frequency and percentage. 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 significant.

Result:

A total of 250 patients were subjected to ERCP procedure in our center between April 1, 2019 and March 31, 2021. The mean age of the included patients was 52±17.8 years, and the number of females was 154 (61.1%). The overall procedure success rate was 93% and the overall complications rate was 7%, the rest of baseline characteristics and ERCP procedure-related data are presented in **table 1**.

Different indications for ERCP procedures are presented in **figure 1** with 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.

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After applying the previously mentioned COVID-19 pandemic prevention and protection measures in our center on the first of April 2020, we found about 5% increase in the volume of cases from 122 cases before COVID-19 to 128 after. Comparison between the two groups showed statistically significant better platelets count and INR, and higher pancreatic amylase level in patients before COVID-19, the rest of variables showed statistically insignificant difference between the two groups, **table 2**. Regarding procedure-related data, there was statistically significant shorter total procedure time in patients after COVID-19 (42 versus 46 minutes, p=0.04) while other variables including indications, CBD diameter, cannulation attempts, cannulation time, overall success rate and complication rate showed statistically insignificant difference, **table 3**.

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

There was statistically significant correlation 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, **table 4**.

Two of the included patients had confirmed COVID-19 infection at the time of ERCP, both were 69 and 80-year-old females with pancreatic head mass compressing the CBD. ERCP procedures were done under safety precautions, because of failed trials of wire-guided cannulation (WGC), biliary access was achieved via transpapillary fistulotomy (TPF) then biliary stent was deployed in total procedures time of 39 and 46 minutes in both cases respectively, with smooth post-procedure coarse. On the other side; 3 out of 9 ERCP team members have caught mild to moderate COVID-19 infection and fully recovered after receiving the proper management in 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 respectively **(18,19)**. Subsequently; certain safety measures became necessary to keep the quality standard of endoscopic procedures in the era of COVID-19 pandemic including use of PPE to help protect patients and health care providers, and requesting certain investigations like chest CT and/or nasopharyngeal swab to help detect patient at high risk of COVID-19 **(19)**. For several reasons including saving resources for COVID-19 patients and reducing the risk of infection, health authorities have put many restrictions upon medical practice including endoscopy.

A Previous study **(20)** about the impact of COVID-19 pandemic on endoscopy services and bowel cancer screening in comparison to pre-COVID concluded a substantial reduction in the average weekly activity for colonoscopy (90%), flexible sigmoidoscopy (91%) and upper endoscopy (86%), while the reduction was only 44% for ERCP procedures. In a web-based survey **(21)** included 55 countries, there was an average 83% reduction in total endoscopy volumes during the COVID-19 pandemic. Interestingly; we noticed a little increase in the volume of ERCP cases during 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 included 31 endoscopy centers located in Northern and Central Italy **(22),** data were retrospectively collected from a total of 804 patients underwent ERCP for different indications. There was about 44% reduction in case volume in the same period (from 1439 in 2019 to 804 in 2020). Only 22/804 procedures (2.7%) were performed in SARS-CoV-2-positive patients, in our study only 2/128 procedures (1.5%) were performed in confirmed COVID-19 cases. The overall complication rate and procedure related deaths in our center were less than that 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 included patients in our study also the different indication for ERCP as malignant biliary obstruction was the most common indication for ERCP in the Italian study in contrary to calcular obstruction in our study. As the screening protocols vary from country to country and from area to another according to the available resources and expertises; the commonly used screening protocols in the previous multicenter study were questionnaire triage in all centers, nasopharyngeal swab in 96.8%, chest computed tomography in 76.7% of the included centers. In our center we used questionnaire triage and clinical assessment for all

patients, chest CT in patient with positive questionnaire and/or clinical suspicion, while the nasopharyngeal swab was spared only for patients with positive CT findings.

Comparison between the use of standard PPE and enhanced PPE in two groups of patients who were subjected to ERCP before and after COVID-19 pandemic respectively was done in a previous study **(23)** that has initially proposed a negative effect of using extra-ordinary infection control measures on the overall outcome of ERCP procedures. However, the result showed that 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 the studied patients in both groups (93 vs 128), the indication for ERCP was calcular biliary obstruction in 88.7% of them. In our study, malignant indications represented collectively about 34% versus 57% for calcular obstruction, and it is worth mention that ERCP procedure is more technically demanding and time consuming in malignant biliary obstruction which might lead to 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 no statistically significant change in the number of ERCP procedures before and after COVID-19 pandemic. This conclusion could be attributed to the emergency indications of most ERCP procedures. A survey study **(26)** included 11 large centers reported several urgent indications that mandate 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 included 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 versus 64/67, $p = 0.034$), however; the difference in the rate of procedure-related adverse events was not significant (1/18 versus 10/67, $p = 0.44$) **(27)**. Our study has included only two COVID-19 confirmed cases, both had had malignant biliary obstruction and subjected to ERCP procedures with successful biliary drainage achieved and no complications reported. Interestingly; our study showed shorter cannulation time and total procedure time after applying COVID-19 protection measures which could be attributed to the used policy of holding training programs and readiness of the endoscopy team

members and all required tools prior to starting procedures.

Through a retrospective analysis of the outcome of an advanced endoscopic procedure which mostly performed on an urgent basis, 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 all aspects of the health services worldwide. **In conclusion;** there is 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)

Variable (n=250)	Mean±SD, (Range)
Age (Year)	52±17.8, (11-90)
Female (Number & Percent)	154 (61.6%)
Creatinine (mg/dl)	1±0.7, (.1-5.6)
Total Bilirubin (mg/dl)	9.4±8.5, (.7-43)
Direct Bilirubin (mg/dl)	8±7.7, (.3-39.8)
INR	1.1±0.3, (.7-4)
Hemoglobin (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, (38-3329)
Pancreatic Amylase (U/L)	97.2±141, (19-1746)
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 & Percent)	232 (93%)
Overall Complications (Number & 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

Variable	Before COVID-19 (n=122)	During COVID-19 (n=128)	Significance
Age (Year)	55	56	.815
Female (Number & Percent)	79 (64.7%)	75 (58.6%)	0.3
Total Bilirubin (mg/dl)	6.6	6.8	.616
Direct Bilirubin (mg/dl)	5.4	5.7	.527
INR	1	1.1	.036
Hemoglobin (g/dl)	12.1	12.1	.914
WBCs (x 10^3)	7.9	8	.555
Platelets (x 10^3)	279	238	.014
ALT (U/L)	102	116	.238

AST (U/L)	97	105	.361
ALP (U/L)	317	314	.381
Pancreatic Amylase (U/L)	71	68	.002
Creatinine (mg/dl)	0.9	0.9	.36

Data presented as medians except female gender presented as number and percent.

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

Variable		**Before COVID-19 (n=122)**	**During COVID-19 (n=128)**	**Significance**
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	.324
Cannulation Time (Minutes)*		9.7±12.8	4.8±7.3	0.01
Number	**1**	59	64	0.066

of Cannulation	**2**	13	7	
Attempts*	**3**	16	30	
	4 or more	31	25	
Total Procedure Time (Minutes)		46	42	0.044
Overall Success Rate (Number & Percent)		113 (92.6%)	119 (92.9%)	0.9
Overall Complication Rate (Number & Percent)		9 (7%)	8 (6%)	0.723

CBD diameter and total procedure time are presented as median, the rest of variables are presented as number and percent. (*) Presented as mean±SD, Cases with failed duodenal intubation were excluded (3 before and 2 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

Variables	**Before COVID-19 (n=122)**		**During COVID-19 (n=128)**	
	Pearson Correlation	**Significance (2 tailed)**	**Pearson Correlation**	**Significance (2 tailed)**
Age (Year)	0.154	.552	-.093	.297
Female (Number & Percent)	-0.063	0.319	0.017	0.849
Creatinine (mg/dl)	-.259	.004	.068	.443
INR	-.157	.084	-.136	.126
Bilirubin (mg/dl)	-.234	.010	-.001	.989
Direct Bilirubin (mg/dl)	-.239	.008	.025	.776

ALT (U/L)	.035	.705	.158	.074
AST (U/L)	-.017	.850	.143	.106
ALP (U/L)	-.079	.386	-.212	.016
Hemoglobin	.173	.056	.248	127
WBCs (x 10^3)	-.099	.280	.153	.085
Platelets (x 10^3)	.006	.949	.082	.356
Amylase (U/L)	-.028	.762	.045	.610
CBD Diameter (mm)	-.058	.525	.152	.086
Number of Cannulation Attempts	-.206	.025	-.366	.000
Cannulation Time (Minutes)	-.262	.004	-.092	.313
Procedure Time (Minutes)	-.184	0.042	-.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

Variables	**Before COVID-19 (n=122)**		**During COVID-19 (n=128)**	
	Pearson Correlation	**Significance (2 tailed)**	**Pearson Correlation**	**Significance (2 tailed)**
Age (Year)	-.075	0.413	-.159	.073
Female (Number & Percent)	0.011	0.902	0.086	0.334

Creatinine (mg/dl)	-.114	.211	-.041	.644
INR	.269	.003	-.070	.435
Bilirubin (mg/dl)	-.092	.316	-.093	.294
Direct Bilirubin (mg/dl)	-.100	.275	-.093	.294
ALT (U/L)	-.065	.478	-.055	.534
AST (U/L)	-.041	.654	-.050	.578
ALP (U/L)	.313	.000	-.058	.514
Hemoglobin	.134	.140	.034	.700
WBCs (x 10^3)	.061	.505	-.159	.073
Platelets (x 10^3)	.054	.558	.191	.031
Amylase (U/L)	.026	.774	.248	.005
CBD Diameter (mm)	-.159	.080	-.112	.210
Cannulation Attempts	.396	0.000	.220	.013
Cannulation Time (Minutes)	.418	0.000	.178	.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,

Figure (1) Different indications in all procedure performed (n=250)

CBDS: Common Bile Duct Stones, CCA: Cholangiocarcinoma, Ph: Pancreatic head

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Others include 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 common bile duct stricture