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ORIGINAL ARTICLE

Endoscopic Retrograde Cholangiopancreatography During the COVID-19 Pandemic: Effects of Enhanced Personal Protective Equipment

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Abstract

Background and Aims Personal protective equipment (PPE) decreases the risk of disease contagion, and because of the COVID-19 pandemic, enhanced PPE (EPPE) is widely used during endoscopic procedures including endoscopic retrograde cholangiopancreatography (ERCP). The aim of this study was to investigate the effects of EPPE on ERCP success parameters compared to standard PPE (SPPE).

Methods ERCP procedures were evaluated retrospectively and ERCP outcomes were compared for similar time periods as before and after the COVID-19 pandemic. Primary outcomes were cannulation time, number of cannulation attempts, cannulation success rate, difficult cannulation rate, undesired pancreatic duct cannulation rate, ERCP-related adverse events, and length of hospital stay.

Results Three hundred and eighty ERCP procedures were examined. One hundred and fifty-nine procedures were excluded due to missing data, previous sphincterotomy or altered anatomy. Of the final eligible sample size of 221 ERCPs, 93 were performed using SPPE and 128 were performed under EPPE. Indications of ERCP and demographic parameters were similar between groups. The majority of the ERCP cases included were for benign biliary obstruction of common bile duct stones (88.7%). No significant differences were detected in overall technical success (91.4% vs 92.2%, $p=0.832$), cannulation success rates (94.6% vs 96.8%, $p=0.403$), cannulation times (median times of both groups were 3 min, $p=0.824$), difficult cannulation rates (37.6% vs 33.6%, $p=0.523$), undesired pancreatic duct cannulation rates (29% vs 22.7%, $p=0.593$), number of cannulation attempts (2.80 vs 2.71, $p=0.731$), ERCP-related adverse events (9.7% vs 10.9%, $p=0.762$), and length of hospital stay (6.63 vs 6.92 days, $p=0.768$) between SPPE and EPPE groups, respectively.

Conclusion Biliary obstructions of common bile duct stones were the major indication of ERCP in the current study. The use of EPPE had no negative effects on ERCP performance in this patient group. ERCP can be effectively performed under EPPE.

Keywords COVID-19 · Endoscopic retrograde cholangiopancreatography · ERCP · Pandemic · Personal protective equipment

Introduction

Because of the COVID-19 pandemic, various professional organizations recommend to use enhanced personal protective equipment (EPPE) to decrease the risk of endoscopists' exposure to the virus during gastrointestinal endoscopic procedures and prevent them from possible infection [1, 2]. In Turkey, EPPE during the COVID-19 pandemic consists of face shields, hairnets, and N95 filtering facepiece (FFP) respirators, in addition to the standard personal protective equipment (SPPE) of water-resistant gloves and gown for all gastrointestinal endoscopic procedures.

Authors Tolga Düzenli and Hüseyin Köseoğlu contributed to conception and design; analysis and interpretation of the data; drafting of the article; critical revision of the article for important intellectual content; final approval of the article.

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Upper gastrointestinal endoscopy procedures are high-risk methods for disease transmission, because close patient contact is needed during the procedures [3, 4]. The use of FFP masks result in different psychological and physiological effects. For example, prolonged usage of FFP masks interfere with respiration, thermal equilibrium, and vision, and they also intervene in communications between clinicians and other health care workers [5, 6]. All of these factors, especially adequate vision are of great importance during ERCP. Because of fogging, face shields, and FFP masks can adversely affect sight and possibly impact endoscopy handling [7]. To the best of our knowledge, there is no study evaluating the effect of EPPE on ERCP success and outcomes.

Taking into account that the COVID-19 pandemic may remain for a long duration, EPPE may be required and used for prolonged times. The aim of this study was to investigate the impact of EPPE on the success and quality outcomes of ERCP.

Materials and Methods

Study Design

This study is a retrospective observational study performed in a tertiary referral center in Turkey. Local ethics committee of Hitit University Faculty of Medicine approved the study with decision number of 312/2020. ERCP procedures which were performed in two similar 6-month time periods—October 1 2019 to March 31 2020 and April 1 to September 31, 2020—were evaluated and compared. The procedures performed in the first time period were done with SPPE, and EPPE was used for the procedures performed in the latter period.

Patient Selection

The laboratory and ERCP reports of patients who underwent ERCP in our endoscopy unit were extracted from the computerized database. Data of patient demographics that included previous abdominal surgery, body mass index (BMI), and medical history were reviewed. The same experienced endoscopist performed all of the ERCP procedures. We excluded patients with altered anatomy and previous sphincterotomy (Fig. 1). The patients who enrolled for analysis were divided into two groups based on the SPPE or EPPE use. Data about the patients' characteristics, indications, procedure details, cannulation success rate, cannulation time, difficult cannulation rate, unintended pancreatic duct cannulation rate, number of cannulation attempts, and length of hospital stay were compared.

COVID-19 Measures

There were a total of 128 patients in EPPE group and 122 of them were tested for COVID and results were as negative. However, there were 6 patients with severe cholangitis that we had decided not to wait for the COVID PCR test. Regardless of that, all of these procedures were performed

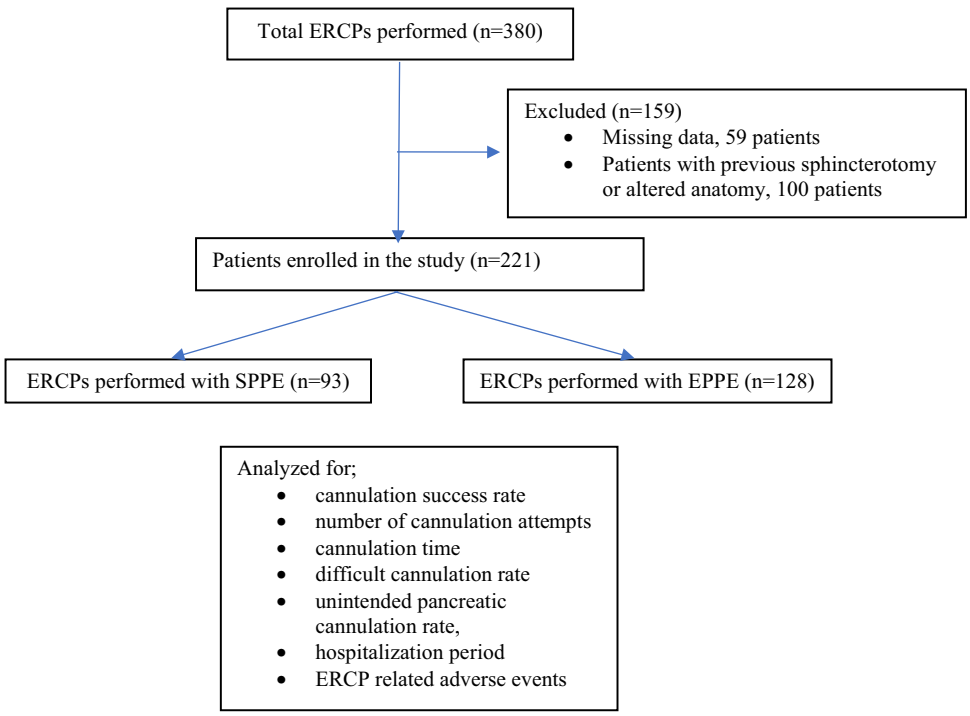

Fig. 1 Patient enrollment and classification

with EPPE consisting of face shields, hairnets, and N95 filtering facepiece respirators, in addition to the standard personal protective equipment of water-resistant gloves and gown (Fig. 2). There were also 4 elective patients who had positive COVID-19 PCR results. We postponed these procedures and referred the patients for follow-up and treatment of COVID-19.

The rotation time due to COVID-19 in the ERCP room was 30 min between patients in the EPPE group.

Endoscopic Procedure

Written informed consent was obtained from the patients and all ERCP procedures were performed by an experienced endoscopist using standard side-view duodenoscopes in appropriate position following overnight fasting.

All procedures were performed under conscious sedation using intravenous midazolam with propofol at the supervision of the attending anesthesiologist. The endoscopist was experienced by over > 1000 ERCPs and there was no involvement of trainees in the procedures. Oxygen supplement was applied when indicated and the patients were monitored continuously with a pulse oximeter, electrocardiography monitoring. For PEP prevention, prophylactic rectal NSAI drugs and intravenous ringer lactate infusion were administered before ERCP. Prophylactic placement of pancreatic stent was performed when the cannulation was difficult, especially when multiple pancreatic duct cannulations occurred. Guidewire-assisted cannulation method was performed in all patients. Needle-knife precut (NKP) and trans-pancreatic sphincterotomy (TPS) were used if cannulation was not successful. Choosing the appropriate cannulation technique was made according to the expertise and preference of the endoscopist which was in accordance with the anatomy of the papilla and the number of unintended pancreatic duct cannulations. All patients were hospitalized for one day after the ERCP for observation of complications.

Fig. 2 Enhanced personal protective equipment consisted of face shields, hairnets, and N95 filtering facepiece respirators, in addition to the standard personal protective equipment of water-resistant gloves and gown

Outcomes

Primary outcomes were overall technical success, cannulation time, cannulation success rate, difficult cannulation rate, unintended pancreatic duct cannulation rate, number of cannulation attempts, stone sizes, biliary and pancreatic stenting, ERCP-related adverse events, and length of hospital stay. These indices are commonly used to evaluate the success and quality of ERCP and they were extracted objectively from the electronic reporting system.

Definitions and Criteria

The ERCP procedures' overall technical success was defined according to the achievement of the pre-procedural goal (e.g., complete clearance of common bile duct stones or biliary stenting for large stones, malignant, and benign obstructions). Difficult cannulation: If the cannulation duration was more than 5 min, the cannulation attempts on the papilla were more than five or the pancreatic duct was cannulated more than twice; the ERCP was defined as difficult cannulation according to the recent guideline of European Society of Gastrointestinal Endoscopy (ESGE) [8]. Cannulation time was defined as the time from the start of cannulation to the time when the guidewire was introduced into the common bile duct. Each touching of the catheter, sphincterotome or guidewire to the major papilla was defined as cannulation attempt.

ERCP-related adverse events were determined according to the modified Cotton criteria described in the ESGE guideline of 2020 [8]. Post-ERCP pancreatitis was defined as new or worsened abdominal pain combined with > 3 times the normal value of amylase or lipase at more than 24 h after ERCP and requirement of admission or prolongation of a planned admission; cholangitis as new onset temperature > 38 °C for more than 24 h combined with cholestasis; bleeding as hematemesis and/or melena or hemoglobin drop > 2 g/dL; perforation as evidence of gas or luminal contents outside of the gastrointestinal tract determined by imaging; hypoxemia as hemoglobin oxygen saturation < 85% and hypotension or hypertension as either a blood pressure value < 90/50 or > 190/130 mmHg or a change in value down or up 20% [8].

Statistical Analysis

Statistical analyses were performed by SPSS software (Statistical Package for the Social Sciences, version 20.0, SPSS

Inc., Chicago, IL, USA). Descriptive statistics (frequency distributions, percentage, mean, median, standard deviation) of the study group were determined. The data were evaluated for normal distribution by Kolmogorov–Smirnov test and by visual parameters (histogram, variation coefficient, skewness, kurtosis etc.). Student t and Mann–Whitney U tests were used for comparisons. Categorical data were analyzed by chi-square test. p values lower than 0.05 were considered as statistically significant.

Results

A total of 380 ERCPs were performed during the aforementioned study period. Fifty-nine ERCP procedures with missing data and 100 patients with previous sphincterotomy or altered anatomy were excluded. Of the remaining 221 ERCPs, 93 were performed using SPPE and 128 were performed under EPPE (Fig. 1). Mean patient age was 66.6 ± 18.2 (min.18–max.97) years. The most common indication for ERCP was biliary stones or sludges (88.7%). There were no significant differences in patient demographic parameters, comorbidities, pre-procedure The American Society of Anesthesiologists (ASA) physical status classification system scores or ERCP indications between both groups (Table 1). Pre-procedure levels of total bilirubin ($p = 0.002$) were significantly higher in EPPE group than in the SPPE group. Also, white blood cells and CRP levels were higher in EPPE group than in the SPPE group but there was no statistically significance.

There were no significant differences in overall technical success (91.4% vs 92.2%, $p = 0.832$), cannulation success rates (94.6% vs 96.8%, $p = 0.403$), cannulation times (3 min vs 3 min, $p = 0.824$), difficult cannulation rates (37.6% vs 33.6%, $p = 0.523$), unintended pancreatic duct cannulation rates (29% vs 22.7%, $p = 0.593$), number of cannulation attempts (2.80 ± 1.98 vs 2.71 ± 2.10, $p = 0.731$), periampullary diverticulum (19% vs 20%, $p = 0.860$), use of precut (9% vs 10%, $p = 0.567$), stone sizes ($p = 0.187$), complete stone removal (83.3% vs 88.4%, $p = 0.128$), biliary stenting (16.1% vs 14.8%, $p = 0.486$), pancreatic stenting (8% vs 12%, $p = 0.371$), ERCP-related adverse events (9.7% vs 10.9%, $p = 0.304$), and length of hospital stay (6.63 vs 6.92 days, $p = 0.768$) between both groups (Table 2). Sedation-related adverse events were intraprocedural, mild, and transient events that did not affect the overall management plan.

Table 1 Patient demographics

	SPPE	EPPE	*p*
Number of patients	93	128	
Age (years)	66.3 ± 19.1	67.4 ± 15.6	0.791
Gender (*n*, %)			0.880
Male	34 (37%)	50 (39%)	
Female	59 (63%)	78 (61%)	
BMI (kg/m^2)	26.9 ± 4.3	26.2 ± 3.7	0.272
Charlson comorbidity index	4 ± 2.5	4 ± 2.2	0.992
Pre-ERCP ASA score	2.9 ± 1.1	3.4 ± 1.3	0.058
Indication of ERCP (*n*,%)			
Choledocholithiasis	84 (90%)	112 (87%)	
Malignancy	8 (9%)	11 (9%)	
Benign obstruction	0 (0%)	3 (2%)	0.205
Bile duct injury	1 (1%)	0 (0%)	
Hydatid cyst	0 (0%)	2 (2%)	
Pre-ERCP lab			
White blood cells, 10^9/L	9.2	10.6	0.218
Hemoglobin, g/dl	13.6	12.4	0.453
Platelets, 10^9/L	221	243	0.078
Total bilirubin, mg/dl	2.53	4.22	0.002
Creatinine, mg/dl	0.9	0.97	0.341
Albumin, g/dl	4.27	3.63	0.285
c-reactive protein, mg/l	36.8	46.8	0.259

ERCP, endoscopic retrograde cholangiopancreatography; *SPPE*, standard personal protective equipment; *EPPE*, enhanced personal protective equipment; *BMI*, body mass index; *ASA*, American Society of Anesthesiologists physical status classification system score

Discussion

This study is the first study in the existing literature to evaluate the effects of EPPE on ERCP performance. Performing ERCP in COVID-19 outbreak areas has a high risk for infection, but ERCP is still commonly required for patients with biliary obstruction and for those whose procedure cannot be delayed until the COVID-19 pandemic resolves. It is considered that ERCP has a high risk for COVID-19 transmission because of airborne droplets, direct contact, contamination by touch, and probable fecal–oral transmission [9]. Because of the high number of asymptomatic patients and the fact that transmission occurs also from asymptomatic patients with COVID-19, and furthermore the high number of false-negative results of virological tests in many cases, it is often challenging to identify all patients with COVID-19 before ERCP. Moreover, symptoms such as fever and abdominal pain are commonly seen in patients who need urgent ERCP, and this makes the differential diagnosis of COVID-19 more complicated. Because of these reasons, we regarded all patients as potential COVID-19 patients regardless of the patients' risk status for COVID-19 [9].

On the other hand, wearing EPPE causes evident physical discomfort to the endoscopist and justifiable concern is present about the impact of EPPE on success rates and quality outcomes of endoscopic procedures. The impact of EPPE on upper gastrointestinal endoscopy and colonoscopy performance was investigated, but the effect of

Table 2 Results

	SPPE ($n=93$)	EPPE ($n=128$)	p
Overall technical success	85 (91.4%)	118 (92.2%)	0.832
Total cannulation rate (n, %)	88 (94.6%)	124 (96.8%)	0.403
Cannulation time (median)	3	3	0.824
Difficult cannulation rate (n, %)	35 (37.6%)	43 (33.6%)	0.523
Unintended pancreatic cannulation rate (n, %)	27 (29%)	29 (22.7%)	0.593
Cannulation attempts (n, mean)	2.80 ± 1.98	2.71 ± 2.10	0.731
Periampullary diverticulum	18 (19%)	26 (20%)	0.860
Use of precut	8 (9%)	14 (10%)	0.567
ERCP for choledocholithiasis-stone size (n)	79	108	0.187
No stone detected	10 (13%)	13 (12%)	
< 1 cm	45 (57%)	67 (62%)	
1–2 cm	20 (25%)	23 (21%)	
> 2 cm	4 (5%)	5 (5%)	
Complete stone removal	70/84, 83.3%	99/112, 88.4%	0.128
Biliary stenting	15 (16.1%)	19 (14.8%)	0.486
For stone	9	9	
For malignancy	5	5	
For others (benign obstruction, bile duct injury, hydatid cyst)	1	5	
Pancreatic stenting	7 (8%)	15 (12%)	0.304
ERCP-related adverse events (n, %)	9 (9.7%)	14 (10.9%)	0.762
PEP	5 (5.4%)	9 (7%)	0.618
Bleeding	0 (0%)	1 (0.8%)	0.272
Perforation	1 (1.1%)	0 (0%)	0.363
Other (cardiovascular, anesthesia etc.)	3 (3.2%)	4 (3.1%)	0.966
Length of hospital stay (days)	6.63 ± 3.81	6.92 ± 4.62	0.768

SPPE, standard personal protective equipment; *EPPE*, enhanced personal protective equipment.

EPPE on ERCP quality outcomes was yet to be elucidated [10, 11]. Our study showed that outcome measures such as cannulation success rate, cannulation time, difficult cannulation rate, unintended pancreatic duct cannulation rates, number of cannulation attempts, and length of hospital stay are not negatively affected by the use of EPPE compared to SPPE. However, the current study had included mostly benign biliary obstructions and may not apply to all ERCP indications. There is little known about this subject in the existing literature. Leeds et al. reported that the native biliary cannulation rate was the same for the pandemic period compared to the previous year (91.7% vs. 91.8% [12]. Zorniak et al. reported that there was a slight but statistically not significant decline in the rate of selective bile duct cannulation rate and the rate of successful extraction of biliary stones, but the urgent treatment success was increased significantly [13]. The authors considered that wearing uncomfortable EPPE may play an important role while performing time-consuming procedures and the decrease of successful extraction of biliary stones with a significant increase of successful implementation of biliary stents may be a result of more conservative approach of big and hard to extract biliary stones in the COVID-19 pandemic. We believe that this concept might be justifiable for the first period of the pandemic, but throughout time, endoscopists got used to the situation of both COVID-19 infection and EPPE, and as a result we found that the ERCP success rates were similar to the pre-pandemic period. On the other hand, one must keep in mind that difficult cannulation might be a confounding factor when difficult and time-consuming cannulation is present, in which EPPE may have negative effects on ERCP performance. Eventually, there was no statistically difference between the groups for this variable in the current study.

One noteworthy finding in our study was that the number of ERCPs remained unchanged, which can be explained by the fact that most ERCP indications are medical emergencies, and delays are not advisable for most instances. Mahadev et al. presented a survey from 11 large academic centers in the New York region and reported indications that were considered urgent enough to warrant proceeding during the pandemic across all centers [14]. For ERCP, the major indication was for the management of obstructive jaundice and cholangitis.

Additionally, due to the fact that the pandemic may exist for a long time and the end of the pandemic is not known, physicians cannot postpone all ERCP procedures to a further period. This finding is in accordance with observations from other countries [13, 15, 16]. No significant differences in urgent ERCP procedures were determined in our study. This finding shows that ERCP is an essential therapeutic procedure, which cannot safely be postponed without harm even during a hazardous pandemic. On the other hand, O'Grady et al. presented a significant reduction of 36.8% in ERCP procedures in March–April 2020 compared to the same period of 2019 [17]. Furnari et al. reported that ERCPs for benign diseases showed an apparent reduction compared to ERCP procedures performed for malign diseases [18]. That is probably associated with adhering to public health guidance to remain indoors, fear of leaving home, and reduced access to healthcare professionals. Part of the reason was also due to many hospitals shutting down and rescheduling elective procedures. We consider that this finding was justifiable for the first months of the pandemic, but despite the fact that COVID-19 have peaked again and still continues, patients are more willing to seek health care as time progresses.

In the present study, pre-ERCP ASA scores in EPPE group were higher than SPPE group, although there was no significance. ASA classification is used to allow the individual risk stratification in association with concomitant diseases and physical status. Higher ASA scores indicate progression of concomitant diseases and decline in physical status. We consider that this finding may reflect the impact of COVID-19 pandemic on the health system. Public health guidance to remain indoors, fear of leaving home, reduced access to healthcare professionals and shutting down of many hospitals may result in progression of concomitant diseases and decline in physical status.

There were no difference regarding ERCP-related adverse events between the groups in the current study. O'Grady et al. mentioned low complication rates for ERCP procedures and concluded that quality performance indicators were not compromised with current restrictions and similar procedural success and complications rates may be expected to continue [17]. Voiosu et al. recently reported the results of 18 ERCP procedures carried out in patients with confirmed COVID-19 [19]. The authors noticed that the rate of procedure-related adverse events was low in both COVID-19 and control groups and ERCP did not seem to have significantly impacted patient safety. Our findings also indicate that EPPE does not have a negative impact on post-ERCP complication rates.

Length of hospital stay was 6.63 days in SPPE group and 6.92 days in EPPE group. Yet there was no significant difference, COVID group's hospitalization period was longer than pre-COVID group. We think that there may be a few explanations for this finding. First, most of the COVID group patients (95.3%) had COVID-PCR test (nasopharyngeal swab) before the procedures which had a time scale of a few hours. Second, the rate of post-ERCP pancreatitis was higher in EPPE group than in the SPPE group which might also contribute to prolonged hospital stay. Third, total bilirubin levels were significantly higher in EPPE group than in the SPPE group and white blood cells and CRP levels were higher in EPPE group than in the SPPE group yet there was no statistically significance. Therefore, the delayed referral of the patients in the COVID group might also contribute to prolonged recovery period and prolonged hospital stay.

We think that there are some reasons as to why there is no negative effect of EPPE on ERCP success. The possible reasons of why we did not find a reduction of ERCP success are as follows: the endoscopist performing ERCP had the chance of removing FFP masks between procedures, he used face shields with antifogging features reducing the impact of misting on vision. Additionally, the endoscopist was experienced in ERCP, therefore cannulation and procedure times were relatively short compared to inexperienced endoscopists, so he was not overwhelmed by EPPE through the procedures.

Conclusion

Stringent PPE requirements are needed during endoscopic procedures, especially ERCP, because of the COVID-19 pandemic. This study suggests that performing a successful ERCP is not affected by EPPE, and ERCP may be performed effectively with the use of EPPE. But, one must keep in mind that the current study had included mostly benign biliary obstructions and does not apply to all ERCP indications.

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Declarations

Conflict of interest The authors declare that there is no conflict of interest with regard to the authorship and/or publication of this article. The authors received no financial support for the research and/or authorship of this article.

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