

Strategies for ERCP complications: A new performer's experience and strategies for beginners to avoid complications

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Abstract

Aim: This study aims to share our experience of our first field experience after endoscopic retrograde cholangiopancreatography (ERCP) training and share our "The starting strategy for new ERCP performer" protocol which we created to prevent severe complications in our first year on field experience

Materials and Methods: 190 ERCP cases performed at Health Sciences University - Kartal Dr. Lütfi Kirdar Research and Education Hospital ERCP unit between June 2018 to November 2019 are documented retrospectively. All the cases were taken to procedure through our protocol rules. The protocol is described fully with details in the text.

Results: A total of 190 (89 female-101 male) patients had undergone ERCP, of which 39 were diagnostic, 151 was therapeutic. 16 (8.4%) cases were aborted during the protocol described points during the ERCP procedure to avoid complications. Five of these cases were referred to another hospital, 7 cases were performed in another session, and 3 cases underwent surgery without performing another session of ERCP due to a given diagnosis of malignancy during ERCP. All other cases are performed regularly with a cannulation success rate of 88%. Complications occurred in 7 (3.6%) cases; 2 cholangitis due to persisting bile stone, 4 pancreatitis (highest hospitalization for 4 days), and one hemorrhage. No surgery needed complications or mortality has been reported.

Conclusion: We believe a new performer can reduce the rate and risk of complications for the first year of his/her to high volume and experienced centers' rate by using a predefined protocol.

Keywords: Complications; ERCP; prophylaxis; protocol

INTRODUCTION

Since the initial introduction of the endoscopic retrograde cholangiopancreatography (ERCP) in 1972 by various authors' approaches to pancreatobiliary system related diseases have begun to evolve rapidly (1,2). Even though ERCP was promising to improve patient comfort compared to open surgical techniques, the complications associated with ERCP were also engrossing. Through early studies to new publications, complication rates varied widely from 0.8% to 45% (3-7). High complication rates and seriousness of complications led to several studies that focused on understanding the effects of lack of practice of new performers on ERCP complications (4,7-12). These studies have shown that high practice rates can lower complication rates. However, new performers have been struggling with complications and having real difficult times in the field during their first year after finishing

the ERCP training. In this study, we wanted to share our experience of our first field experience after ERCP training and share our "The starting strategy for new ERCP performer" protocol, which we created to prevent severe complications in our first year on-field experience.

MATERIALS and METHODS

All ERCP procedures were performed by the same endoscopist who has finished his two years of ERCP education in another institute. All ERCP cases were performed by the endoscopist in the Health Sciences University - Kartal Dr. Lutfi Kirdar Research and Education Hospital ERCP unit. Cases from June 2018 to November 2019 are documented retrospectively. A database has been created by Numbers for MAC v6.2.1 by Apple Inc. Patients were selected and procedures have been performed according to "the starting strategy for new ERCP performer" which is described in Table 1.

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Table 1. Protocol used for "The starting strategy for new ERCP performer "**Patient Selection**

Sphincterotomy will not be performed to patients whose bile stone is not clearly differentiated from tumor.

If the tumor is pre-diagnosed or tumor has been diagnosed during ERCP only therapeutic procedure and incisional biopsy will be done, stenting will only be applied if necessary.

If INR is above 1.5 case will be postponed if the case is an emergency TDP will be given to the patient.

The patient will not be taken to procedure only with sedatives every patient will be taken to procedure with the anesthesia team.

Procedure Cautions

Indomethacin 100 mg per rectal will be administered prior to the procedure if not contraindicated.

1000 cc Saline solution will be given 1 hour before the procedure and 200 cc/h continuous IV saline admissions will be administered during the procedure.

If sphincterotomy is planned prophylactic antibiotic will be administered just before cannulation.

Patient must be fixed to the table from hip and upper extremities must be restrained appropriately for avoiding patients reach to the endoscope.

Sphincterotomy will be applied only with cauteries cut function. Coagulation will only be used if bleeding occurs and does not stop after 7 minutes.

If any incident occurs which provokes pancreatitis (multiple cannulation of wirsung, contrast leakage to wirsung, edema or cut of minor papilla.), wirsung will be stented immediately.

Precut or needle sphincterotomy will not be used until the case is an emergency case or bile stone is seen and stuck on the papilla.

Hyoscine n-butylbromide will be administered Intravenous routinely (start:5 mg; the maximum dose will not exceed 20 mg).

Contrast injection to papilla in hard cases for finding a way to choledoc is forbidden.

If anatomical variation which will harden the procedure is seen during ERCP, or position cannot be taken in front of papilla easily cannulation try will not exceed 10 minutes or more than three attempts. After 10 minutes or three attempt procedure will be aborted.

After Procedure

Every patient will be monitored after the procedure for 12 hours; if no pain or symptom occurs, the patient will be discharged and will come to control at 36th hour.

Six hours of oral closure will be performed after the procedure.

A blood test will be performed at 12th hour and 36th hour if necessary time can be shortened.

After the procedure, patient will be highly hydrated intravenously if not contraindicated (min:3500cc/24h).

If the patient has pain nonsteroidal anti-inflammatory drugs will be preferred and the patient will be hospitalized while stopping oral intake.

All criteria will be bypassed and ERCP will be performed immediately if the case is an emergency case. (emergency case includes: cholangitis needs surgery or cholangitis which is not controlled or partially controlled by anti biotherapy) or post-surgical complication case.)

All patients signed informed consent for the procedure. All cases without contraindication had screened by MR cholangiography (MRCP) before ERCP. If the patient has a contraindication for MRCP, then hepatobiliary US and computerized tomography (CT) has been used for pre-diagnosis. ERCP was defined as therapeutic when endoscopic sphincterotomy, precut, or drainage had been carried out alone or together. If a biopsy has been taken and sphincterotomy has not been performed, the case has been considered as diagnostic. Patients are monitored and followed up to 12 hours and had a physical examination at the hospital after the procedure and screened for WBC, Hb, Hct, Plt, AST, ALT, ALP, GGT, LDH, amylase, total and direct bilirubin, at the 12th hour and

36th hour after discharge. If any complication occurred, patients have been hospitalized immediately. The study was approved by Dr. Lutfi Kirdar Kartal Research and Education Hospital Ethics Committee with the registration number of 5141745.

RESULTS

A total of 190 (89 female-101 male) patients had undergone ERCP of which 39 were diagnostic, 151 was therapeutic. The average age of patients was 61.9 (19-93). The pre-procedure diagnosis and results of the cases were as follows: 110 cases were choledocholithiasis, 15 cases underwent ERCP for fistula after surgery complication (3 pancreatic fistula, 12 biliary fistula), 16

cases were cholangitis due to choledocholithiasis and taken to the procedure without our protocol restrictions as an emergency case, 49 cases were non diagnosed obstructive jaundice or referred due to suspicion on tumor (among these patients 27 patients had a tumor, one patient had cholestasis due to echinococcus granulosus, 16 were choledocholithiasis and 5 were free of pathology), 14 cases referred to ERCP with various pre-diagnosis canceled by the endoscopist without performing ERCP due to unnecessary indication and these patients are followed up for three months in every two weeks to confirm of no need for ERCP treatment.

16 (8.4%) cases were aborted during the protocol described points during the ERCP procedure to avoid complications. Five of these cases were referred to another hospital, 7 cases were performed in another session, 3 cases

underwent surgery without performing another session of ERCP due to given diagnosis of malignancy during ERCP. None of these patients had any complications due to ERCP.

The average procedure time of therapeutic cases was 30.1 (min:13 - max: 85) minutes. The average cannulation time was 5.9 minutes (min:1 - max 25). Our cannulation success was 88%, with 133 successful cannulations out of 151 therapeutic patients.

Complication occurred in 7 (3.6%) cases; 2 cholangitis due to persisting bile stone, 4 pancreatitis (highest hospitalization for 4 days) and one hemorrhage diagnosed by melena (stopped at first 24 hours, no transfusion needed). No surgery needed complications or mortality has been reported (Table 2).

Table 2. Summary of demography and outcomes of ERCP cases

Parameter (n=190)	Value
Age (years)	61.9 (19 - 93)
Gender (F/M), n	89 / 101
Diagnostic / Therapeutic, n	39 (21%) / 151 (79%)
Indication	
Choledocholithiasis, n	110 (58%)
Cholangitis, n	16 (8%)
Non-prediagnosed or tumor suspicious, n	49 (26%)
Diagnosed tumor	27
Diagnosed choledocholithiasis	16
Free of malign pathology	5
Parasitic disease	1
Fistula, n	15 (8%)
Pancreatic	3
Biliary	12
Complications, n	7 (3.7%)
Pancreatitis	4
Cholangitis	2
Hemorrhage	1
Cannulation success (success / therapeutic total), n	133/151 (88%)
Cannulation time (minute)	5.9 (1 - 25)
Total therapeutic time (minute)	30.1 (13 - 85)
Cases aborted during ERCP due to protocol, n	16 (8.4%)
ERCP performed in another session	7
Referred to another hospital	5
Underwent surgery due to tumor diagnosis	3

Continuous data are described by mean (range)

DISCUSSION

ERCP is a procedure that has a long learning curve and hard to expertise. There are many papers which mention ERCP's end of the learning curve between 180 to 400 procedures (13-15). Even though many cases are needed to perform the procedure effectively, reducing the complication rate is beyond these volumes. Many studies are focusing on the complication rates for ERCP

performers in low and high-volume centers and new ERCP performer's complication rates. In some papers, It is accepted that high-volume center is where ERCP cases are performed more than 200, low-volume center is vice versa too (12,16). According to these studies, experience and low-volume have been shown as a significant factor for complications. In a prospective multicenter study, Loperfido et al. studied consecutive 2769 patients from six

low-volume centers. They announced that low-volume center and precut were independent risk factors for overall significant complications (17). Another multicenter study, including 1157 patients collected from 15 centers to assess post ERCP pancreatitis performed by Cheng et al. shows that operator experience is a high-risk factor for post ERCP pancreatitis (12). A multicenter study focuses on the volume of the center to the effect of post ERCP complications. The study consists of 2629 hospitals and 199,625 patients, which shows no mortality difference in low and high-volume centers but shorter length of stay and lower procedural failures in high-volume centers (18).

Many studies describe methods for avoiding complications. These studies recommend methods and techniques to lower failure and complication and mortality rates (6,10,19-21). However, studying in a low volume center and being an inexperienced endoscopist is a problem that needs to be assessed. In our series, we performed 190 ERCP cases with a complication rate of 3.6%, which is similar to the rate of high-volume and experienced center. We believe that this success is not originated from the endoscopist, thus a benefit of the protocol. 8.4% of the patients (31% referred to another hospital other are postponed or operated for tumor) have been aborted when we see risk according to protocol and canceled 14 cases (not included in the ERCP cases) due to unnecessary ERCP indication. We believe aborting, postponing, or canceling these cases was the critical point on our success.

There are also recommendations for avoiding ERCP related complications in literature. In a prospective randomized study performed by a single endoscopist on 400 patients showed that, using a soft-tipped catheter instead of traditional method prevented post-ERCP pancreatitis on patients (19). A review published in 2003 by freeman describes pharmacologic agent studies (gabexate and somatostatin) for the prevention of pancreatitis and mentions studies on prevention of hemorrhage by injecting epinephrine to site before sphincterotomy (6). Using nonsteroidal anti-inflammatory drugs prior to study, intrapancreatic stenting, using antibiotics before the procedure are described in multiple studies for preventing pancreatitis (20). Throughout these studies, a guideline was performed in 2012 by the American Society for Gastrointestinal Endoscopy Standards of Practice Committee describing the multivariate analyzed risk factors of ERCP and recommendations to avoid them (3). Even these studies and recommendations lighten the path of ERCP procedure; complications occur and ERCP performers are always in doubt to avoid complications while performing ERCP.

This study is not only representing new ERCP performer's experience but also presents a protocol designed for avoiding the most common causes of ERCP complications. The primary reason to develop the protocol in this study was to prevent as many complications as possible and cause less harm to the patient during the first inexperienced

year of solo performing of ERCP. In this study, we have seen that even an inexperienced performer can lower his/her complication rates and perform ERCP more reliably by avoiding or postponing risky procedures and using some prophylactic cautions. After gaining enough experience, the protocol may be less strict, and the performer may take on more risky procedures as becoming an expert in ERCP.

It has been shown in this study that our complication rates are similar to the experienced centers. It is inevitable that there is a difference between our case difficulties to the experienced centers. However, our study is aiming at the results of choosing the right case for inexperienced ERCP performer by designing a protocol and using precautions to avoid complications described in the literature.

CONCLUSION

This study shows that by avoiding or postponing cases inappropriate due to the experience of ERCP performer and building a protocol for the prophylaxis of most common ERCP complications. Even though we have seen advantages of our protocol, each performer should modify the protocol depending on his/her deficiencies to take maximum advantage. We believe a new performer can reduce the rate and risk of complications for the first year of his/her to high-volume and experienced center rate by using a predefined protocol.

Competing interests: The authors declare that they have no competing interest.

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