

The impact of gastroenterology fellowship involvement on the ERCP outcomes

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ABSTRACT

Aims: This study aimed whether the companionship of the gastroenterology fellowships to operators performing high-volume ERCP, would adversely affect the safety and success of the procedure.

Methods: This retrospective observational study included 964 patients with naïve papilla who underwent ERCP between February 2019 and May 2022. Procedures with fellowship involvement were compared with procedures performed only by the expert operator in terms of cannulation success, procedure time, cannulation time, unintended PD cannulation, difficult cannulation, cannulation techniques, and post-procedure adverse events.

Results: The two groups were similar in terms of procedure difficulty, successful cannulation in the first session, overall successful canulation, unintended PD cannulation, difficult cannulation rates, and cannulation techniques. The median procedure time was significantly higher in the fellowship involvement group compared to the other group (p=0.008). There was no difference between the two groups in terms of adverse events after the procedure (p>0.05). Procedure difficulty were found an independent risk factor of adverse events in the multivariate analysis (Odds ratio: 2.3; 95% Cl 1.4-3.6; p<0.001).

Conclusion: Our study showed that the involvement of gastroenterology fellowships in the ERCP procedure prolonged the procedure and cannulation time but did not decrease the technical success and did not increase adverse events.

Keywords: ERCP training, gastroenterology fellowship, post-ERCP complications, endoscopic retrograde cholangiopancreatography

INTRODUCTION

As a result of the recent developments in Endoscopic Retrograde Cholangiopancreatography (ERCP) and other advanced endoscopic procedures and the widespread use of these procedures, the training and competence of operators have become one of the current issues in recent years.¹ Qualification and its measurement are of great importance in ERCP, considering the central position of ERCP in these procedures. Many guidelines on measuring competence in ERCP have been published.^{2,3} Studies mostly focus on the relationship between the volume and duration of trainees and proficiency of trainees.

The number of studies evaluating the effect of trainee involvement in ERCP training on ERCP outcomes is relatively few.⁴ In a recent study, investigating the effect of trainee involvement on ERCP outcomes, it has been found that trainee involvement does not increase the risk of ERCP

complications and has no effect on the technical success of the procedure.⁴ In the study, trainee endoscopists have been defined as persons with negligible ERCP experience.

In the literature, there are also studies on the success and proficiency of fellowship operators in gastroenterology education in ERCP procedures.5 In previous publications, Accreditation Council for Graduate Medical Education (ACGME) has stated that 3-year gastroenterohepatology training may not be sufficient in terms of competence in ERCP. For this reason, postgraduate ERCP training programs have become increasingly widespread in recent years.⁶

In the literature, previous studies on ERCP training have not specified the status of participants in the procedures as pre- or post-graduation during their training.⁷ In this study,

Corresponding Author: Rasim Eren Cankurtaran, drcankurtaran88@gmail.com



Department of Gastroenterology, Faculty of Medicine, Ankara Yıldırım Beyazit University, Ankara, Turkey

²Department of Gastroenterology, Ankara City Hospital, Ankara, Turkey

³Department of Internal Medicine, Ankara City Hospital, Ankara, Turkey

we aimed to shed light on whether the companionship of the gastroenterology fellowships to operators performing high-volume ERCP, would adversely affect the safety and success of the procedure.

METHODS

Ethical Statement

The study was carried out with the permission of Ankara City Hospital No:2 Clinical Researches Ethics Committee (Date: 22/12/2021, Decision No: E2-21-1170), and the study was conducted in accordance with the Declaration of Helsinki guidelines. Signed informed consent was obtained from each participant prior to the study.

Study Design

This study was designed as a retrospective cohort study in a single tertiary center gastroenterology clinic. ERCP procedures of patients with naive papilla between February 2019 and May 2022 were reviewed for the study. Among those, procedures with grade 1 and grade 2 difficulty were included in the study. Patients who were hospitalized in other centers and whose clinical follow-up records were missing were also excluded from the study. Grade 3 procedures were also excluded since only experienced operators were involved and total procedure number was low. Demographic data, procedure indications, laboratory, and imaging data, ERCP findings, procedure-related complications, and all clinical follow-up data of all patients were obtained from electronic database and patient files.

Endoscopic Procedures

ERCPs were performed with a lateral scope (TJF 190; Olympus Optical, Japan) by an experienced operator (yearly ERCPs 800<) or by fellows (4 in total) under the supervision of the same experienced operator. The experienced operator in the procedures attended by the Fellowships intervened in the procedure verbally or practically at any stage of the process when deemed necessary. In ERCP procedures, selective biliary cannulation was first attempted classically, primarily with the guidewire method. If there was a failure in selective biliary cannulation, other methods such as a double guidewire, pre-cut techniques, and transpancreatic biliary sphincterotomy (TPBS) were performed. The routine Cannulation times and total procedure times of the procedures were also recorded.

Training Program

In Turkey, gastroenterology training is performed as a 4-year internal medicine residency followed by 3 years of upper specialization. Fellowships in our clinic are trained in upper gastrointestinal endoscopy and colonoscopy procedures in the first 2 years of gastroenterology residency. Fellowships who performed more than 2000 upper gastrointestinal endoscopies and more than 1000

colonoscopies in total participated in these procedures for ERCP training in the last year. Due to variations in the rotation schedules, some procedures were performed with fellowship participation while others were performed by an expert operator without a fellowship.

Definitions

Procedures resulted with deep selective biliary cannulation were defined as successful cannulation. The difficulty level of ERCP procedures was graded according to the Schutz scale.8 ERCP-related adverse events of all patients after the procedure were defined according to the criteria set by an international consensus.9 In addition, cardiopulmonary complications which developed in some patients during the ERCP procedure, were defined as adverse events. The time between the visualization of the major papilla and the selective biliary cannulation was defined as cannulation time, while the time from the beginning to the end of the procedure was defined as total procedure time. Difficult cannulation was defined according to the criteria set by a recently published guideline. According to these criteria, biliary cannulation could not be achieved within 5 minutes and/or 2 or more unwanted pancreatic cannulations were considered as difficult cannulation. 10

Study Outcomes

The primary outcome of the study was to determine the effect of fellowship participation on ERCP success and post-procedural adverse events. Outcomes of the ERCP procedures between fellowship involvement and expert operator were compared in terms of cannulation success, procedure time, cannulation time, unintended pancreatic duct (PD) cannulation, difficult cannulation, and cannulation techniques. In addition, the data of both groups were compared in terms of adverse events such as post-procedural complications, need for intensive care unit (ICU), and mortality.

Statistical Analysis

Data analyses were conducted using Statistical Package for the Social Sciences (SPSS 22.0 for Windows, Chicago, IL, USA) software. The variables were investigated using visual (histograms and probability plots) and analytical methods (Kolmogorov-Smirnov tests) to determine whether they were normally distributed. In reporting descriptive statistics, data were expressed as mean ± standard deviation (SD) for normally distributed numerous variables, median (minimum-maximum) for noncontinuous numerous variables and ordinal variables, and as frequencies and percentages (%) for nominal variables. The $\chi 2$ tests, Fisher's exact or Likelihood ratio tests were used to compare nominal variables or categorical variables between the groups. In addition, the independent samples T-test was used to compare continuous numerous variables and the Mann-Whitney U test was used to compare the noncontinuous numerous variable or ordinal variables between the groups. A p-value of < 0.05 was considered statistically significant. Variables thought to affect post-ERCP side effects were first analyzed by univariate logistic regression. Then, the significant variables were included in the multiple logistic regression model and the odds ratio (OR) of the variables was calculated.

RESULTS

A total of 1003 patients with naive papilla underwent ERCP between February 2019 and May 2022. Five patients who met the Schultz 3 criteria and 34 patients whose follow-up was conducted at another center were excluded from the study. The remaining 964 patients were included in the study.

Table 1 shows the comparison of demographic characteristics and laboratory findings between the groups. There was no significant difference between the two groups in terms of age, gender, history of cholecystectomy, comorbidities and laboratory findings (p>0.05). There was a significant difference in the indication for the procedure between the two groups (p=0.006).

The two groups were similar in terms of procedure difficulty8, successful cannulation in the first session, overall successful canulation, unintended PD cannulation, difficult cannulation rates, and cannulation techniques (p=0.879, p=0.783, p=0.338, p=0.239, p=0.644, p=0.345, respectively). The cannulation time was significantly different between the two groups (p<0.020). The median procedure time was significantly higher in the fellowship involvement group compared to the other group (p=0.008).

Sphincterotomy and stone removal rates were significantly higher in the procedures without fellowship involvement group compared to the other group (p=0.027, p=0.001, respectively) (Table 2).

There was no difference between the two groups in terms of adverse events after the procedure (p>0.05) (Table 3).

Table 3. Comparison of post-ERCP side effects of procedures with and without fellowship participation					
	Procedures of only expert operators, n (%)	Procedures with fellows involvement, n (%)	p		
PEP, n (%)	48 (12.1)	80 (14.1)	0.377*		
Bleeding, n (%)	10 (2.5)	25 (4.4)	0.125*		
Perforation, n (%)	3 (0.8)	8 (1.4)	0.540*		
Cholangitis, n (%)	2 (0.5)	4 (0.4)	0.699*		
Cardiopulmonary complications	5 (1.3)	8 (1.4)	0.847*		
Need for ICU, n (%)	7 (1.8)	18 (3.2)	0.178*		
Mortality, n(%)	4 (1.0)	8 (1.4)	0.771**		
Any adverse events, n (%)	65 (16.4)	117 (20.6)	0.102*		
PEP: Post-ERCP Pancreatitis, ICU: intensive care unit, *: $\chi 2$ tests **: Fisher exact test					

Univariate analyses revealed that age (p=0.022), procedure difficulty (p<0.001), total procedure time (p<0.001), cannulation time (p<0.001), and difficult cannulation (p<0.001) were possible risk factors of adverse events. When these five possible risk factors were entered into multivariate analysis, only procedure difficulty was found an independent risk factors of adverse events (Odds ratio: 2.3; 95% Cl 1.4-3.6; p<0.001) (Table 4).

	Procedures of only expert operators N=396	Procedures with fellowship involvement N=568	
Age mean (SD)	59.27 (17.92)	60.09 (18.19)	0.489*
Female sex n(%)	230 (58.1)	311 (54.8)	0.306**
History of cholecystectomy n(%)	74 (18.7)	83 (14.6)	0.092**
Comorbidities HT DM Cardiovascular diseases Chronic obstructive pulmonary diseases Chronic kidney diseases Malignancy	161 (40.7) 74 (18.7) 74 (18.7) 23 (5.8) 8 (2) 14 (3.6)	254 (44.7) 113 (19.9) 111 (19.5) 30 (5.3) 23 (4) 32 (5.6)	0.210** 0.641** 0.740** 0.724** 0.079** 0.288**
Indications for the procedures, n (%) CBD Stones Malignant stricture of the bile duct Bile leak or trauma Other	330 (83.3) 28 (7.1) 21 (5.3) 17 (4.3)	444 (78.2) 56 (9.9) 18 (3.2) 50 (8.8)	0.006**
Laboratory data Tbil Dbil AST ALT GGT CRP	2.80 (0.3/24.0) 1.7 (0.1/16.0) 154.0 (12/1843) 203 (7/1496) 381 (10/2415) 12 (0.10/358.0)	2.90 (0.2/25.1) 1.80 (0.1/17.7) 147.5 (9.0/2072) 216.5 (4/1139) 353.5 (5/3090) 13.6 (0.1/243.0)	0.678*** 0.589*** 0.989*** 0.572*** 0.680*** 0.973***

	Procedures of expert operators, n (%)	Procedures with fellowship involvement (%)	p
Procedure difficulty level n (%) Grade 1 Grade 2	354 (89.4) 42 (10.6)	506 (89.1) 62 (10.9)	0.879*
Successful cannulation in the first session n (%)	378 (95.5)	540 (95.1)	0.783*
Overall success cannulation n (%)	392 (99.0)	558 (98.21)	0.338*
Cannulation time, n (%) <5 min 5-10 min 10 <min< td=""><td>293 (74.6) 54 (13.7) 46 (11.7)</td><td>405 (72.1) 58 (10.3) 99 (17.6)</td><td>0.020*</td></min<>	293 (74.6) 54 (13.7) 46 (11.7)	405 (72.1) 58 (10.3) 99 (17.6)	0.020*
Total procedure time (min) Median (min-max)	25 (13/72)	27 (11/76)	0.008**
Unintended PD cannulation None 1 time 2≤ times	301 (76) 35 (8.8) 60 (15.2)	411 (72.4) 47 (8.3) 110 (19.3)	0.239***
Difficult cannulation, n (%)	111 (28.0)	167 (29.4)	0.644*
Cannulation technique Wire-guided cannulation Double guidewire technique Pre-cut technique TPBS Failed cannulation	304 (76.8) 77 (19.4) 9 (2.3) 2 (0.5) 4 (1.0)	433 (76.2) 97 (17.1) 21 (3.7) 7 (1.2) 10 (1.8)	0.345***
Sphincterotomy Stone removal (Balloon or basket) Plastic stent placement Covered metal stent placement EBD Brush sitology	392 (99.0) 291 (73.5) 250 (63.1) 4 (1) 21 (5.3) 39 (9.8)	550 (96.8) 357 (62.9) 333 (58.7) 10 (1.8) 33 (5.8) 74 (13.0)	0.027* 0.001* 0.169* 0.338* 0.736* 0.338*

PD: pancreatic duct, TPBS: trans-pancreatic biliary sphincterotomy, EBD: endoscopic balloon dilatation, *: $\chi 2$ tests, **: Mann-Whitney U test, ***: Likelihood test, bold values show statistical significance.

Variables	No-Adverse Events	Adverse Events	Univariate p value	Multivariate p value	OR (95%CI)
Gender			0.072	-	-
Male	354 (83.7)	69 (16.3)			
Female	428 (79.1)	113 (20.9)			
Age	59.1 ± 19.1	62.5 ± 17.6	0.022	0.052	
Tbil	2.9 (0.2 - 25.1)	2.65 (0.20 - 24.0)	0.921	-	-
Procedure difficulty leve	el				
Grade 1	714 (83.0)	146 (17.0)	< 0.001	< 0.001	2.3 (1.4 - 3.6)
Grade 2	68 (65.4)	36 (34.6)			
Total procedure duration	26 (11 - 76)	29 (12 - 68)	< 0.001	0.585	-
Cannulation time					
<5 min	601 (86.1)	97 (13.9)	< 0.001	0.936	-
5-10 min	76 (67.9)	36 (32.1)			
10 <min< td=""><td>98 (67.6)</td><td>47 (32.4)</td><td></td><td></td><td></td></min<>	98 (67.6)	47 (32.4)			
Difficult cannulation					
No	593 (86.4)	93 (13.6)	< 0.001	0.078	-
Yes	189 (68.0)	89 (32.0)			
Fellowship involvement					
No	331 (83.6)	65 (16.4)	0.103	-	-
Yes	451 (79.4)	117 (20.6)			
Tbil: total bilirubin, Con	tinuous variables with n	ormal distribution were	expressed as mean	±standard deviation, while	others were expresse

Tbil: total bilirubin, Continuous variables with normal distribution were expressed as mean±standard deviation, while others were expressed as median (min - max). Categorical variables were shown as n (%)

DISCUSSION

The most important results of the study were that the involvement of fellowship in ERCP does not decrease cannulation success and does not increase post-procedural adverse events. The fact that the involvement of fellowship in the ERCP procedure significantly increases the total procedure and cannulation time is another important result of study.

The fact that ERCP has been included in the therapeutic treatment of many pancreaticobiliary diseases with the developments in recent years and has become increasingly widespread has revealed the importance of ERCP training. On this subject several guidelines have been published in many regions and each guideline has put forward different competency criteria. Those guidelines sought to answer the question of the minimum number of procedures an independent ERCP operator should perform during the ERCP training.

While discussing this very important issue, another question has been raised, regarding how fellowship involvement in ERCP training will affect the results of ERCP. In this concept, current studies in the literature revealed conflicting results. In a recent study of 1843 ERCP procedures, fellowship involvement and control group were compared in terms of adverse events. Contrary to expectations, moderate and severe adverse events were found to be significantly higher in the control group. We believe that this study is very valuable with its multicentred and prospective nature. However, the fact that serious and moderate adverse events were higher in the control group is the most important controversial finding of the study. The reason for these controversial results may be the fact that the data were collected from different databases due to the multicentred nature of the study, and some centers in the study performed ERCP in low volumes.4 However, in another study by Voiosu,¹³ the principal investigator of the above article, no differences were found in terms of adverse events between procedures with and without fellowship involvement. The fact that this study was single centered supports our hypothesis about the previous study. In our study, no significant difference was found between both groups in terms of complications. Notably, PEP was fount to be the most common adverse event with a rate of 13.3% in total. Although this is slightly higher than the sample studies mentioned above, it seems to be an acceptable rate considering that the incidence of PEP in meta-analyses in the literature ranges between 8.4 and 14.7%.14 In addition, almost all patients who developed PEP had mild pancreatitis. Severe PEP developed in only 3 patients in the group with fellowship involvement followed by 2 patients in the other group. Mortality post-procedural cardiopulmonary secondary

complications were observed in 2 patients. In 1 patient from both groups, mortality developed due to prolonged ICU hospitalization (i.e., infection) after the surgical intervention for ERCP related perforation.

The success of the procedure has also been among the main topics investigated in studies with fellowship involvement. While some studies have compared only cannulation success, 13,15 some studies have compared the technical success of the procedure as a total evaluation of manoeuvres such as biliary cannulation, stone removal, and stent placement. 4,16 Frost et al. 15 found no difference in successful biliary cannulation rates between the groups with and without trainee involvement in a study of 219 procedures. In addition, both studies by Voisu et al. 4,13 reached similar findings and demonstrated that trainee involvement did not affect cannulation and technical success. In a Chinese prospective study, no significant difference was found between the trainee involvement group and the control group in terms of technical success. 16 Similar results were also observed in our study and no significant difference was found between the two groups in terms of successful biliary cannulation. Notably, successful biliary cannulation rates in both groups were above 90%, which is the quality criterion of the European Society for Gastrointestinal Endoscopy (ESGE).¹⁷ It was observed that there was a difference between the two groups in terms of stone removal and sphincterotomy rates among the interventions performed during the procedure. We think that the higher rate of stone removal in the expert operator group may be due to the higher number of patients who underwent ERCP with the indication of Common Bile Duct stones in this group.

Whether the fellowship involvement may lead to an increase in the number of difficult cannulations is undoubtedly another important concern for expert operators. Fellowship initiation of the procedure and unsuccessful cannulation attempts may result with an increase in difficult cannulation situations which may cause some operators to have negative thoughts about ERCP training. Voiosu et al.¹³ reported that trainee involvement prolonged cannulation time and increased the use of the pre-cut technique. Although difficult cannulation was not defined in the study, it is suggestive in this respect that pre-cut techniques, which are among the methods used in the case of difficult cannulation, were found to be higher in the trainee group. In this study, the duration of cannulation was longer in the fellowship involvement group, which is consistent with this study. However, no difference was found between both groups in terms of difficult cannulation and cannulation techniques.

The most important limitation of this study is that the study was single-centered and retrospective. The low number of fellowships and expert operators is another limitation of the study. Finally, the fact that there may be inter-fellowship variability accompanying the procedures, which may affect the results, can also be counted among the limitations of the study. However, we think that the high number of subjects recruited for the study is sufficient.

CONCLUSION

This study demonstrated that the involvement of gastroenterology fellowships in the ERCP procedure prolonged the procedure time yet did not decrease the technical success. Notably, another important result of this study is that fellowship involvement is not an independent risk factor for ERCP related adverse events. ERCP training of fellowships under the supervision of experienced operators may ensure that independent ERCP operators and centres may become more common in the future, but this statement requires further studies.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of Ankara City Hospital No:2 Clinical Researches Ethics Committee (Date: 22/12/2021, Decision No: E2-21-1170).

Informed Consent: Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process: Externally peer reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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